

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY

3
4 IN RE: VALSARTAN PRODUCTS
5 LIABILITY LITIGATION

CIVIL ACTION NUMBER:
19-md-02875-RBK-KMW

EVIDENTIARY HEARING
via ZOOM TELECONFERENCE

6
7 Mitchell H. Cohen Building & U.S. Courthouse
8 4th & Cooper Streets
9 Camden, New Jersey 08101
10 March 2, 2022
Commencing at 9:32 a.m.

11 B E F O R E:

THE HONORABLE ROBERT B. KUGLER
UNITED STATES DISTRICT JUDGE

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E X A M I N A T I O N S

<u>Witness</u>	<u>Direct</u>	<u>Cross</u>	<u>Redirect</u>	<u>Recross</u>
STEPHEN LAGANA, MD BY MS. LOCKARD	6			
DIPAK PANIGRAHY, MD BY MR. TRISCHLER BY MR. NIGH	54	93		
MAHYAR ETMINAN, PharmD, MSC BY MS. BROWN BY MR. VAUGHN	98	144		

1 (PROCEEDINGS held via Zoom before The Honorable
2 ROBERT B. KUGLER at 9:30 a.m.)

3 THE COURT: Well, I think we're all here. And good
4 morning, everybody. As you know, I'm Judge Kugler.
5 What we need to do this morning is set some ground
6 rules.

7 The first is, if you're not participating, we would
8 appreciate if you would go off the video, because we have a
9 lot of people on the screen, and we have a court reporter who
10 is trying to figure out who is saying what to whom.

11 The second thing is, I need you to identify now, for
12 us, who is going to do the questioning of the witness, and
13 who, on the odd chance there might be an objection, will be
14 speaking on behalf of the plaintiff.

15 So who is going to be doing the questioning?

16 MS. LOCKARD: Your Honor, Victoria Lockard.

17 THE COURT: Ms. Lockard, you have some feedback going
18 on big time.

19 MS. LOCKARD: I understand. Our tech is taking care
20 of that in the room.

21 THE COURT: Okay. In fact, I barely heard what you
22 said, Ms. Lockard.

23 Are you doing the questioning or --

24 MS. LOCKARD: Yes, Your Honor. I'll be doing the
25 questioning.

1 THE COURT: And then who will be speaking on behalf
2 of the plaintiff, if it's necessary to raise any objections?

3 MR. SLATER: Good morning, Your Honor, Adam Slater
4 for the plaintiffs. I'll be, quote/unquote, defending
5 Dr. Lagana at the hearing.

6 THE COURT: Okay.

7 MS. BROWN: Good morning, Your Honor. This is Alli
8 Brown, and I'll be doing the questioning for Dr. Etminan later
9 today.

10 THE COURT: Okay.

11 MS. BROWN: Thank you.

12 THE COURT: By the way, did we work out the timing
13 later today? I know one of the counsel had a potential
14 conflict with another case.

15 MS. BROWN: It was me, Your Honor. And we're hopeful
16 that if necessary, I understand the plaintiffs are amenable
17 to -- with the Court's permission, a short 30-minute recess at
18 2:00 if we are in the middle of the questioning.

19 THE COURT: Sure.

20 MS. BROWN: Thank you, Your Honor.

21 THE COURT: No problem.

22 THE COURT: Mr. Trischler, how are you? You wanted
23 to say something.

24 MR. TRISCHLER: I was just going to finish if the
25 Court wanted the full game plan for today.

1 I will be doing the questioning of Dr. Panigrahy.

2 THE COURT: He's next, as I understand it. Correct?

3 MS. BROWN: I believe that's the order, yes, sir.

4 MR. SLATER: Correct.

5 THE COURT: Mr. Slater, are you going to, quote,
6 defend that one also?

7 MR. SLATER: I am not going to. That will be I think
8 Mr. Nigh.

9 MR. NIGH: That's correct. That would be me, Your
10 Honor, Daniel Nigh.

11 THE COURT: Then why don't we get started with
12 Dr. Lagana.

13 Dr. Lagana, I see you on here. Would you raise your
14 right hand.

15 THE WITNESS: Yes, sir.

16 STEPHEN LAGANA, MD, PLAINTIFFS' WITNESS, after being
17 duly sworn, was examined and testified as follows:

18 THE COURT: State your full name.

19 THE WITNESS: Stephen Michael Lagana.

20 THE COURT: All right, Ms. Lockard. He's all yours.

21 DIRECT EXAMINATION

22 BY MS. LOCKARD:

23 Q. Good morning, Dr. Lagana.

24 A. Good morning.

25 Q. You and I haven't had an occasion to meet quite yet, have

1 we?

2 A. Not to my knowledge.

3 Q. Last week you submitted a certification in further
4 support of your general causation opinions in this case.

5 Correct?

6 A. Correct.

7 Q. And that was dated February 23, 2022. Correct?

8 Do you have that in front of you?

9 A. I do.

10 Q. Just --

11 A. Yes, that is the correct date.

12 Q. All right. And did you draft that certification
13 yourself?

14 A. No.

15 Q. Okay. So you didn't write that certification, the
16 lawyers did?

17 A. The lawyers drafted it with my input. We discussed
18 everything in it in great detail, and they transcribed my
19 thoughts.

20 Q. Now, you understand we're not here today to discuss the
21 challenges defendants have made as to your qualifications as a
22 pathologist. Do you understand that?

23 A. That's my understanding, yep.

24 Q. And is it your understanding that one of the reasons
25 we're here today is to discuss the challenges defendants have

1 made to your methodology in arriving at your conclusions?

2 A. Correct.

3 Q. And your methodology in this case was to evaluate and
4 take into account the various categories of medical and
5 scientific literature and evidence discussed in your report
6 and in your deposition. Correct?

7 A. Yes. As I stated, I applied a weight of evidence
8 methodology and applied the guidelines of Sir Bradford Hill.

9 Q. Exactly. And so essentially what you did in terms of
10 your methodology is you applied Bradford Hill, you did a
11 weight of the evidence analysis, you did a research project,
12 and you looked at the articles and literature that were
13 generated based on your research and rendered opinions based
14 on those -- that research alone. Correct?

15 A. I think that what you just described gets to the -- gets
16 to the essence of what I did.

17 Q. Now, just for background, you are an anatomic
18 pathologist. Correct?

19 A. Correct.

20 Q. You spend 75 percent of your time on clinical commitments
21 and reviews of specimens. Right?

22 A. Correct.

23 Q. And your professional time, when you're not doing legal
24 work like today, is first and foremost clinical work, then
25 administrative, which has continued to increase, then teaching

1 and then research?

2 A. Absolutely not.

3 MR. SLATER: I'm sorry, Your Honor. I'm very
4 hesitant to object, because I do understand what Your Honor
5 said earlier. I don't -- and I certainly don't want to
6 disrupt. I'm just concerned that we're not within the
7 parameters Your Honor set.

8 MS. LOCKARD: Your Honor, if I may, Dr. Lagana, he
9 has set forth a methodology in this case that defendants have
10 challenged as being outside of his normal expertise and
11 practice in the scope of his duties.

12 I'm not challenging -- we are not challenging or
13 getting into his background credentials and qualifications,
14 how many papers he's written and that sort of thing. But when
15 this Court gave us the parameters at this hearing, the
16 Judge -- you were very specific. You said, we need to know if
17 this is something that the witness does outside of litigation,
18 and if there wasn't litigation or compensation involved, that
19 he would apply the very same methodology that he has applied
20 in this case.

21 So I am not getting into his background, but I do
22 think we have a need -- a fair opportunity to get into his
23 methodology and how it differs from his normal work.

24 THE COURT: How is this any different from what you
25 raised in your motion?

1 MS. LOCKARD: Well, it is -- there are certainly
2 questions in -- issues in the motion that bear on this which
3 is why we are trying to get this testimony in the record today
4 to support the arguments that we made in our motion.

5 THE COURT: Well, you cited extensively to his
6 deposition testimony in your motion papers. I'm well aware of
7 the fact that you assert that he does not follow the same
8 methodology he follows in his normal daily activities as a
9 pathologist. I get that. Really, I do.

10 The point of this is really the question about what
11 he put in his certification. So let's -- I mean, I'm going to
12 give you some leeway to get some background information done,
13 but let's please focus on his certification. Okay?

14 Thank you.

15 MS. LOCKARD: Understood, Your Honor. We'll move
16 forward.

17 BY MS. LOCKARD:

18 Q. In terms of your certification, you make reference in it
19 to a differential diagnosis. Correct?

20 A. Correct.

21 Q. And in your practice as a pathologist, you can and
22 frequently do diagnose cancers without giving an etiology of
23 the cancer. True?

24 A. You know, in a general sense, it's not always required to
25 provide an etiology, but there are certainly plenty of

1 examples, not terribly rare examples, in which providing an
2 etiology is absolutely expected of an anatomic pathologist.
3 So there's no real blanket answer to that. It's sometimes yes
4 and sometimes no. It depends if it's clinically useful or
5 not.

6 Q. Well, the truth of the matter, Dr. Lagana, is that the
7 etiology of a cancer essentially never goes into your report.
8 Isn't that right?

9 A. No, that's not right. No.

10 Q. Do you have a copy of your deposition with you?

11 A. Uh-huh.

12 Q. And we can pull that into the chat feature potentially if
13 we have that access of others.

14 MS. LOCKARD: But Your Honor, may I read from
15 Dr. Lagana's deposition?

16 MR. SLATER: We'd just request that the pages and
17 lines be identified so that we can all get to those first.

18 MS. LOCKARD: Sure.

19 THE COURT: I would like to -- give us a page,
20 please.

21 BY MS. LOCKARD:

22 Q. Absolutely. Turn to page 80, Dr. Lagana, line 15.

23 A. Sure.

24 Q. Let me know when you're there.

25 A. Uh-huh.

1 Q. When my partner, Ms. Cohen, was deposing you in your
2 sworn deposition back on August of 2021, you were asked the
3 question at line 15: Have you ever used those words in a
4 report?

5 And your response, line 17, was, and I'll read: The
6 etiology of a cancer essentially never goes into a report.

7 Did I read that correctly?

8 A. Yep.

9 Q. And so even if you diagnose a lung cancer, you don't say
10 lung adenocarcinoma, smoking related. You just put lung
11 adenocarcinoma. True?

12 A. For lung adenocarcinoma, that's true. And when I
13 answered the question previously, I stated that there are some
14 cancers in which the etiology is clinically relevant and
15 expected that a pathologist will include it, and there are
16 some that it is not.

17 So lung cancer for the most part is an example where the
18 etiology is assumed in most cases and the pathologist would
19 not include that in a report.

20 And I am aware of the testimony that I gave, that you
21 cited. And in looking back on it, it was inartful.

22 And I think if we look at further testimony, specifically
23 on page 87, when Ms. Cohen continued -- I'm sorry, I'm still
24 answering.

25 Am I allowed to finish my answer?

1 Q. I would like for you to answer the question. I
2 understand there's no direct testimony allowed. And I think
3 you have answered my question, Dr. Lagana.

4 THE COURT: Ms. Lockard, you need to let the witness
5 finish. And if you don't think it's responsive, if you need
6 the assistance of the Court, you can ask for the Court's
7 assistance, but we have to let the witnesses finish their
8 testimony. Okay? Thank you.

9 MS. LOCKARD: Understood.

10 BY MS. LOCKARD:

11 Q. Go ahead, Doctor.

12 A. Thank you. As the questioning in my deposition
13 continued, examples came to my mind where actually it is very
14 important for an etiology to be included in a report. And I
15 brought those out during deposition, specifically on page 87
16 where I talk about the need to identify human papillomavirus
17 related to cancers of the oral cavity as opposed to
18 smoking-related cancers of the oral cavity. And the reason
19 for that is because the human papillomavirus-related cancers
20 respond quite well to radiotherapy.

21 And so it is true on page 80 I gave an answer that if I
22 had more time to think or if I could redo it, I would put it a
23 little bit differently. But as we went on with questioning,
24 clearly there are times when I do give an etiology for a
25 particular patient's cancer.

1 Q. Well, human papillomavirus is not one of the claimed
2 cancers that's at issue in this litigation, is it, Doctor?

3 A. Well, I was speaking of an example; I was not speaking
4 directly to this litigation.

5 Q. And you submitted an errata to your deposition, is that
6 right, where you had a chance to read your deposition and make
7 any corrections?

8 A. I don't recall submitting any errata.

9 Q. Well, nonetheless, your chosen choice of words were --
10 were that the etiology never goes into a report.

11 And in some other examples, you were asked about, well,
12 have you ever used the words "pharmaceutical-induced cancer"
13 in your pathology reports? And the answer is no. Correct?

14 A. I would be -- so pharmaceutical-related injury has gone
15 into my reports dozens or hundreds of times, but
16 pharmaceutical-related cancer, no.

17 Q. That would not be something you would put in your
18 report -- in a pathology report you generated. Correct?

19 A. Well, the state of knowledge previously, there -- there
20 aren't many examples that I can think of of
21 pharmaceutical-related cancer prior to this issue coming to
22 light. So this is not something that I would have put in a
23 report previously. I'm not sure that I would agree that I
24 would never put it in a report going forward.

25 Q. All right. Well, this issue came to light, and I believe

1 you were retained back in 2018. Correct?

2 A. It seems a little early to me, but I don't totally
3 recall.

4 Q. So you don't know when the issue of nitrosamines in
5 valsartan was first discovered and reported by the FDA?

6 A. Oh. That is 2018. I was talking about when I was
7 retained I don't recall.

8 Q. So since 2018, you've never put in a pathology report
9 you've generated the words "pharmaceutical-induced cancer" or
10 "valsartan-induced cancer." Correct?

11 A. Correct.

12 Q. And as a matter of fact, a patient's history in taking
13 NDMA is not something that would normally be provided to you,
14 is it?

15 A. On the scale of carcinogenesis, this is still a very new
16 issue, so, you know, before 2018, there would have been no
17 real reason, at least with respect to medications, to include
18 that sort of history on a pathologic requisition. What
19 happens in the future, I don't know.

20 Q. Okay. Well, Dr. Lagana, if you could turn with me to
21 page 83 of your deposition, line 1.

22 A. Okay.

23 Q. You were asked: And sitting here today, you can't think
24 of any time when you thought that something was NDMA or NDEA
25 induced. You can't come up in your mind of any instance where

1 you thought that was the cause or genesis.

2 And your answer was: I think a patient's exposure
3 history to NDMA is not something that would normally be
4 provided to me. It's not something that would typically enter
5 my thinking.

6 Were those your words, Doctor?

7 A. Sorry, what page and what line were you talking about?

8 Q. Page 83, line 1, sir.

9 A. 83. Okay. Sorry, I was on 81.

10 Q. No problem.

11 A. Yep, that's what I said.

12 Q. All right. And before this valsartan litigation and your
13 meeting with Mr. Slater in the fall of 2020, you had never
14 done any research outside of the litigation on NDMA or NDEA.
15 True?

16 A. True.

17 Q. And prior to this litigation, the question of whether
18 ingestion of NDMA or NDEA as an impurity in valsartan and
19 whether that can cause cancer in humans had never even come up
20 in your practice. Correct?

21 A. I wouldn't have expected it to, but no.

22 Q. But as a scientist or a clinician or an MD, you had never
23 looked at this issue before. Correct?

24 A. Well, I wouldn't say that. I mean, it depends how
25 specific you want to define this issue as. Certainly I had

1 some background knowledge of nitrosamines and what they are
2 thought to do before I entered into this litigation. I did go
3 to medical school, and I performed a residency and fellowship.
4 Q. I understand. But the specific question I'm asking you
5 is, as a scientist or a medical doctor, prior to being
6 retained, you had never looked at the issue of whether
7 nitrosamines in valsartan causes cancer. That's a true
8 statement. Right?

9 A. Yes. When Mr. Slater gave me this question, I approached
10 it with an open mind. I didn't have a preconceived sense that
11 the amount of nitrosamine in valsartan would or would not
12 cause cancer. I went through the literature, and I performed
13 a literature review the same way I would if I was writing a
14 review article of which I've written several.

15 Q. Right. And we'll get to that in a moment.

16 But my question to you is that you've been retained by
17 Mr. Slater before, in the Benicar litigation. Right?

18 A. Correct.

19 Q. And in the Benicar litigation, the diagnostic approach
20 you took there was standardized, and it was the approach
21 utilized in your clinical practice. Right?

22 A. I am both a clinician and a researcher. Research is my
23 second largest responsibility at work. And so I -- there are
24 clinical methods that I use. If Mr. Slater were to want to
25 ask me about a particular patient in this matter, I would look

1 at the slides and the history in the same way I described in
2 Benicar when multiple cases were presented to me.

3 In Benicar, I also looked at the question of general
4 causation. And in that sense, I reviewed the literature in
5 the same way I do here, which is to take an open -- open mind,
6 look through the literature, weigh the evidence, and use my
7 judgment to draw a conclusion.

8 Q. Well, in Benicar, you started with a review of clinical
9 information for the patients and the slides for those
10 plaintiffs. Correct?

11 A. I don't remember which I did first.

12 Q. Okay. Take a look at page 104 of your deposition,
13 please, sir.

14 A. Okay.

15 Q. Down on line 16, you were asked: And then when we get
16 into Benicar in 2016 in your report, or 2017, you said, quote,
17 the diagnostic approach I take to such cases is standardized
18 and is the approach utilized in my clinical practice in
19 connection with the studies of authors in the peer-reviewed
20 medical literature and presentations given at major
21 professional meetings.

22 I start with the review of very basic clinical
23 information, generally limited to the presenting symptoms, for
24 example, diarrhea, and then begin my slide review. Right?

25 And your answer was: Remains true.

1 Next question: And that's how you do your clinical work
2 also. Correct?

3 And you said yes.

4 Is that testimony still accurate, sir?

5 A. 100 percent, but we're conflating clinical work and
6 research work.

7 Q. Right. I understand. But my point is that the
8 standardized approach you described as what you used in
9 Benicar is not the same approach you used in valsartan where
10 you didn't have clinical patient information, data and slides.
11 Correct?

12 A. I'll rephrase what I said before, which is -- more
13 accurately is you're conflating clinical work and research.

14 If I was asked to review a particular patient's case and
15 determine whether I believed that individual person's cancer
16 was caused in part or in total by valsartan, I would follow
17 the exact process that I described in this snippet that you
18 just read. That's how I approach a clinical case.

19 As a researcher, I have written many review articles in
20 which I did not personally review any cases. I looked at the
21 literature. And those have been peer-reviewed, and some of
22 them have been widely cited. So in my second role as a
23 physician researcher, the researcher part, that does not play
24 out in the same fashion as looking at a particular patient's
25 pathologic material does.

1 Q. I'm just simply asking you about your methodology in
2 Benicar as an expert witness versus your methodology in the
3 valsartan litigation as an expert witness.

4 Do you understand?

5 A. The difference is -- there's a difference between general
6 causation and specific caution. And the things that you're
7 talking -- the examples that you're reading are the way I
8 would approach the question of specific causation, not the way
9 I would necessarily approach the question of general
10 causation.

11 Q. And in this case, though, you're not being asked to give
12 a specific causation opinion. True?

13 A. Thus far I have not been asked to opine about any
14 specific patient.

15 Q. Now, in your practice, in your research engagements,
16 you've never researched to publish an epidemiology review
17 answering the question of general causation. Correct?

18 A. Well, I've written several review articles with
19 subcategories on epidemiology, specific subheadings of
20 epidemiology as well as causation. So I think that that is an
21 incorrect -- it's a very, very precise wording that you used
22 there. I don't quite know exactly how to answer it.

23 But the -- but if the general question is, have you ever
24 done research studies dealing with epidemiology and causation,
25 the answer to that is absolutely. And they've been published

1 in the peer-reviewed medical literature.

2 Q. But you've never published an article that answers the
3 question, based on a literature review, does exposure X cause
4 cancer in the general population. Correct?

5 A. I'd need to take a few minutes to look through my
6 bibliography.

7 Q. Well, I'm sure plaintiffs' counsel can address that with
8 you on redirect if needed.

9 Let me change gears for just a moment.

10 In looking at your certification, you represent that you
11 took into account the various categories of medical and
12 scientific literature. Correct?

13 A. Correct.

14 Q. But your discussion of valsartan in your report was
15 focused almost exclusively on NDMA. True?

16 A. NDMA is by far the most prevalent nitrosamine in humans,
17 and so, you know, the majority of the research that's
18 available to review does deal with NDMA. But there are
19 certainly examples in my report where I speak to the potent
20 carcinogenicity of NDEA, such as -- just give me one second --
21 the Thresher paper and the Zheng paper on pancreatic
22 adenocarcinoma.

23 Q. And those --

24 A. And also --

25 Q. Go ahead.

1 A. That's okay. I'm done.

2 Q. Right. And so it's true that NDMA is by far the most
3 commonly studied nitrosamine of the two. You agree with that.
4 Right?

5 A. I do.

6 Q. Now, despite there being significantly more literature
7 addressing NDMA than NDEA, you felt it was appropriate to
8 extrapolate NDMA literature in rendering your NDEA opinions.
9 Correct?

10 A. I wouldn't put it in such a black and white phraseology.
11 I did review original medical literature related specifically
12 to NDEA. I gave two examples a moment ago. I don't know that
13 those are the only examples, but they're the ones that come to
14 mind. And furthermore, I went with the -- I did also follow
15 the guidance afforded by WHO who has said that the two should
16 be looked at equivalently.

17 Further, I read what FDA said about the issue. And
18 actually, FDA set the acceptable maximum limit of NDEA quite a
19 bit lower than NDMA, implying that they too consider it more
20 dangerous even than NDMA.

21 So given imperfect evidence, not as robust as NDMA, as
22 you said, I addressed it in as scientific a method as I
23 could -- as I could. And I think I did do that fairly.

24 Q. But the only two peer-reviewed, published articles you
25 can cite to that address NDEA are Thresher and Zheng. Right?

1 A. No, I don't agree with that at all. Those are the two
2 that are on the top of my head. I mean, I did not study as if
3 I was going to be given an exam on this. I'm happy to go
4 through the report again and look at the details of
5 everything. The fact that only two of them come to my mind is
6 really immaterial. That's a question of my memory, not a
7 question of what I looked at.

8 Q. Well, certainly you expected you would be asked these
9 questions today. Correct?

10 MR. SLATER: Objection.

11 BY MS. LOCKARD:

12 Q. About --

13 MR. SLATER: I'm sorry, Your Honor, again, I'm very,
14 very, very hesitant to object, but the word "NDEA" doesn't
15 even appear in this certification. Again, I'm being very,
16 very restrained, but I would object at this point and ask to
17 get back on course.

18 MS. LOCKARD: Well, Your Honor --

19 THE COURT: Counsel, where are we going with this?
20 He doesn't discuss NDEA in this certification.

21 MS. LOCKARD: Well, correct, but he does say in his
22 certification in paragraph 3 that I evaluated and took into
23 account various categories of medical and scientific
24 literature and that that formed the basis for his methodology.

25 My point is that the various categories of medical

1 and scientific literature did not include NDEA literature.

2 THE COURT: Well, but paragraph 3 is in response to
3 what the defense raised about null hypothesis. And he's
4 trying to explain where he began. It has nothing to do with
5 NDEA. So let's move on, please.

6 BY MS. LOCKARD:

7 Q. Okay. Dr. Lagana, the question you were asked to answer
8 in this case is whether ingestion of NDMA and NDEA as a
9 contaminant or impurity of valsartan is a cause of cancer in
10 humans. True?

11 A. Well, I would say the question was -- basically I agree
12 with you. But just to make the wording a little bit more
13 refined, I would say the question I was asked to answer was,
14 is the NDMA and NDEA that contaminated valsartan pills
15 probably or a probable carcinogen to the humans who ingested
16 those pills or not. And I did approach that question from a
17 neural standpoint, weighing the evidence, positive and
18 negative studies and equivocal studies, all of which I
19 considered, and I reached a judgment, which is in my report.

20 Q. Well, Dr. Lagana, if you could turn to your deposition,
21 page 21, line 17. Let me know when you're there.

22 A. Uh-huh.

23 Q. You were asked, you understand -- and again, in this
24 report you start with a sentence that says: This report sets
25 forth my opinions with regard to the question of whether

1 ingestion of NDMA and NDEA as a contaminant or impurity of
2 valsartan can cause cancer in humans. Can cause cancer in
3 humans.

4 Did I read that correctly?

5 A. Yes. And I believe that's what I just said.

6 Q. Well, the question, you would agree, of whether NDMA or
7 NDEA can cause cancer in humans is a different one from
8 whether it is a probable human carcinogen. Right?

9 A. I --

10 Q. I'll move on, Dr. Lagana.

11 You've heard and read that the scientific method should
12 start with a null hypothesis, which is a hypothesis that there
13 is no association of causation unless it's proven otherwise.
14 Right? You've heard that.

15 A. Yeah. The null hypothesis is the statistical starting
16 point of any scientific experiment and it's why we set a
17 p-value for significance at .05. So if I do an experiment and
18 I get a positive result and the p-value is .51, that's
19 really -- or sorry, .49, that's really saying that it's more
20 likely than not that my experiment is true. But it's only
21 2 percent more likely, so it's -- so because we have to start
22 with the null hypothesis in statistics, we as a medical and
23 scientific community have set the typical acceptable p-value
24 as .05.

25 So meaning that, you know, there has to be less than a

1 5 percent chance that an association is -- is a false -- a
2 false signal for us to take the results as positive.

3 Q. But you don't believe you were required to start from the
4 null hypothesis because you didn't perform a statistical
5 analysis. Right?

6 A. Well, we can colloquially talk about null hypothesis in
7 that you should keep an open mind. And I did keep an open
8 mind. I approached this question without a preconceived
9 concept that NDMA or NDEA in valsartan pills were going to
10 cause cancer in humans. I approached it with a open mind and
11 a neutral starting point, and I read the literature and
12 reached my judgment.

13 Q. Well, in your certification you attempt to explain your
14 commentary on the report about your assumptions going into the
15 case by saying that you were simply discussing the concept of
16 a differential diagnosis. Correct?

17 A. I'm sorry, my assumptions about -- I'm not sure I
18 understand exactly what you're asking me.

19 Q. Well, in your report, and what we asked you about on
20 cross-examination in your deposition and what we raised in the
21 briefing, is a comment that you made in your report on page 11
22 and 12 that states: In any patient who develops cancer and is
23 known to have a significant exposure to a probable human
24 carcinogen, it should be assumed that the carcinogenic
25 exposure increased the risk or contributed to the cancer.

1 That was from your report. Correct?

2 MR. SLATER: Objection. It's not an accurate reading
3 of what the report says. It's an inaccurate paraphrase.

4 BY MS. LOCKARD:

5 Q. Okay. Let's take out the report and turn to page 11 and
6 12, Dr. Lagana.

7 A. Sure.

8 Can I respond now or wait --

9 Q. Let me ask my question.

10 A. Sure.

11 Q. So if you put down -- about halfway down the page there's
12 a bold heading. And the heading says: Does NDMA likely cause
13 cancer in humans at the levels in the contaminated valsartan?
14 Correct?

15 A. Yes.

16 Q. And is that -- that's the header you drafted yourself.
17 Right?

18 A. Correct.

19 Q. You authored it?

20 A. Yes.

21 Q. And that is the general causation question, is it not,
22 does NDMA likely cause cancer in humans at the levels in the
23 contaminated valsartan?

24 A. Absolutely.

25 Q. That's not a specific causation inquiry, is it?

1 A. That, no. That statement does not refer to specific
2 causation. It's a general causation question.

3 Q. So if you follow along with me, third sentence after this
4 general causation heading --

5 A. Uh-huh.

6 Q. -- you state: Therefore, for any patient who develops
7 cancer and is known to have a significant exposure to a
8 probable human carcinogen (the levels documented above
9 constitute a significant exposure in my opinion), it should be
10 assumed that the carcinogen -- or excuse me, carcinogenic
11 exposure at least increased the risk or contributed to the
12 subsequent cancer, unless there is a convincing body of
13 evidence to suggest that the carcinogenic insult is null with
14 respect to the specific cancer in question.

15 So first of all, did I read it correctly that time?

16 A. Definitely.

17 Q. Okay. Embedded in this sentence is the assumption that
18 you're representing should be made that a carcinogenic
19 exposure at least increased the risks or contributes to the
20 cancer unless there's convincing evidence otherwise. That's
21 the essence of your statement. Correct?

22 A. Well, again, we're conflating the idea of a particular
23 patient with the idea of general causation. So as it states
24 very clearly -- I'm not done.

25 As it states very clearly in this sentence, for any

1 patient who develops cancer. And as it goes on to say, it
2 should be assumed that the carcinogenic exposure at least
3 increased the risk or. So a carcinogen is something that
4 increases the risk of cancer. It's basically definitional.

5 And so what I'm talking about in this sentence is how I
6 would approach a particular patient if the general causation
7 question had already been firmly established. For example, if
8 I see a patient who has been smoking cigarettes for 60 years
9 and develops a lung cancer, it would be wildly inappropriate
10 to say, hmm, I wonder -- let me take a few years to study --
11 you know, to start researching whether it's possible that
12 cigarettes can cause lung cancer.

13 The research is established. The association and
14 causative nature of the relationship is clear. And as a
15 physician treating a specific patient, not answering a general
16 question, I would apply -- I would use the applied medical
17 literature to answer the question.

18 Q. Well, I understand the explanation that you've given in
19 the certification, Dr. Lagana, but the fact is, you're not
20 being asked in this case to make a specific causation
21 determination. Correct?

22 A. I have not thus far been asked to make a specific
23 causation -- to opine about the specific causation in any
24 specific patient.

25 So this -- this sentence that we're talking about here

1 really doesn't even relate to the question of general
2 causation. It's quite clear because it does say for a patient
3 in it.

4 Q. Well, and that's my point as well. If these statements
5 don't relate to the question at hand, it's not helpful to the
6 exercise today, is it, Dr. Lagana?

7 A. Give me a moment to think about how I'd like to answer
8 that, please.

9 Well, look, I'm not a professional witness. I'm a
10 doctor. I perform research. Perhaps I put more thinking or I
11 explain more of my thinking in more depth than was needed to
12 in this report, and it has certainly given people who are
13 motivated to misunderstand me tremendous opportunity to
14 misrepresent what I said, even though the specific words are
15 in the sentence, including for any patient.

16 Q. And I certainly don't intend to misrepresent you, Doctor,
17 but these are your words. You wrote this report. Correct?

18 A. And the words are true and correct. You keep
19 misunderstanding them or misstating their meaning, when I
20 believe we've said several times at this point that it relates
21 to dealing with a specific patient if the science is already
22 settled.

23 If the defense believes that the science is totally
24 settled, that the amounts of NDMA in these pills are probable
25 human carcinogen, then, I mean, we could just -- you should

1 settle the case now.

2 Q. Well, you understand, don't you, that the science isn't
3 settled with respect to general causation, unlike your
4 cancer-smoking analogy. Right?

5 A. Well, I think the science is less mature than cigarette
6 smoking and cancer, but I have looked through quite a bit of
7 literature, all of which is cited or most of which is cited in
8 my report. And I have given weight to the various forms of
9 evidence, and I have come to the conclusion, the conclusions
10 that are stated in my report.

11 So I -- to me, it is certainly more likely than not that
12 the amounts of NDMA in contaminated valsartan are carcinogenic
13 in humans.

14 Q. Exposure to cigarette smoke is a known carcinogen.
15 Correct?

16 A. Yes.

17 Q. It's a group 1 carcinogen as determined by IARC. Right?

18 A. Yes.

19 Q. You're aware, that's not the case with NDMA or NDEA.
20 It's not a known carcinogen according to IARC. Correct?

21 A. It's a probable human carcinogen according to IARC.

22 Q. Now, I understand that -- this language that you have put
23 under -- in your report under the general causation heading,
24 you now say in your certification that that really goes to a
25 differential diagnosis.

1 But no --

2 A. It was --

3 Q. -- nowhere in your report do you even talk about
4 differential diagnosis. The words "differential diagnosis"
5 don't even appear in your report, do they?

6 A. I'd have to have it virtual -- on my computer and
7 control-F it to know for sure, but that statement is an ex --
8 it starts -- it's an introductory statement to how a doctor
9 approaches a particular patient.

10 And then I get into the, you know, dozens of studies
11 regarding NDMA and NDEA in human cancer. And those are the
12 studies that form the basis of my general causation opinion.

13 These sentences that have been plucked out and
14 misrepresented in my opinion are background sentences about
15 how I would approach a specific patient with cancer, not how I
16 would answer a general causation question.

17 Q. Right. And that's not surprising given that 75 percent
18 of your time is dealing with specific patients, correct, as
19 opposed to answering a general causation question?

20 A. Yeah. Earlier you mentioned that my -- you kind of tried
21 to get into my job description. And yes, clinical medicine,
22 anatomic pathology, is 75 percent of my life.

23 But the next largest area is research. And also, I don't
24 want to draw some phony distinction between clinical practice
25 and general causation of disease. Pathology is the study of

1 disease. That absolutely includes the causation of disease.
2 So thinking about, reading about and talking about causation
3 of disease is part and parcel of what I do almost every day.

4 I'm a teacher as well. That time when I'm doing clinical
5 work, I'm also often about half that time, I have a trainee
6 with me, and I'm explaining to that trainee causes,
7 manifestations, everything else that's part and parcel of
8 disease, which is absolutely a pathologist's business.

9 Q. Doctor, did you apply the null hypothesis in this case,
10 yes or no?

11 A. I didn't do a statistical analysis, so I didn't use null
12 or not null hypothesis. But colloquially, I did approach it
13 with an open and neutral position, and I looked at the
14 literature to convince me one way or the other.

15 Q. Did you adhere to the scientific method?

16 A. Yes, to the extent that you can when you're not
17 performing experiments. I mean, the scientific method is
18 hypothesis-driven -- generally speaking is hypothesis-driven
19 experimental work. I didn't do any experiments. I didn't
20 have a hypothesis.

21 As I've mentioned before, I have written several review
22 articles in the peer-reviewed medical literature. And that
23 entails exactly what I did here, which is to pick a topic. In
24 this case I was provided a topic. And look at what I
25 considered to be the relevant original research and use my

1 judgment to form an opinion based on the weight of the
2 evidence. That's what I did.

3 Q. So just so I understand, so you did not start with a
4 hypothesis when you approached this case?

5 A. That's true.

6 Q. And your position is that's not required because you
7 didn't do any original clinical research, and you didn't do
8 any statistical work. Right?

9 A. Correct. I started with a neutral mindset. I had no
10 particular opinion one way or the other.

11 Q. In your description and explanation of your methodology
12 and process for reaching a conclusion, you likened this case
13 to a scenario of whether jumping out of a ninth floor building
14 causes harm.

15 Do you remember that discussion?

16 A. I think you're misrepresenting the discussion. I did use
17 that analogy, but I don't believe it was in the context of
18 whether -- of any specific case. I think it was a general
19 statement.

20 Q. Well, your position was that in some situations, you can
21 just use a little bit of common sense rather than the null
22 hypothesis. Right?

23 A. In some situations, yes. In a general sense, yes. I
24 never said that that's what I did here or that that statement
25 even has anything to do with this litigation.

1 Q. Right. Obviously, this is not one of those situations
2 where the conclusion relies on common sense. Right?

3 A. Well, any conclusion worth making usually requires a
4 little bit of common sense, but for the most part, I would
5 agree with you, that to have a conclusion here requires a
6 careful analysis of the literature, the medical and scientific
7 literature, and requires one to -- at some level, I mean, one
8 does have to make a judgment. There are a number of papers.
9 In my opinion, most of them clearly go in a certain direction,
10 and that's using the weight of evidence. I reached my
11 conclusion. But there does -- there is an element of human
12 judgment in this matter.

13 Q. Right. But if a conclusion can be reached based on
14 common sense, then we don't need experts like yourself to come
15 in and explain it to a jury who has already possessed their
16 own common sense. Right? That's my point.

17 A. Sure. Of course, there's no -- common sense does not
18 answer this question by itself, no.

19 Q. So you don't agree that the Bradford Hill methodology
20 itself requires that -- that requires a null hypothesis in the
21 beginning of the review prior to applying the nine viewpoints?

22 A. Well, Bradford Hill is a guideline. It's a way to
23 evaluate the epidemiologic and other forms of literature, but
24 originally epidemiologic.

25 I think -- I think it requires -- to apply it fairly

1 requires starting from a neutral position, which is what I did
2 here. Whether you want to call that the null hypothesis, it's
3 sort of misusing the term. So I do think if you start with a
4 preconceived answer and just cherry-pick stuff to support your
5 preconceived answer, that would not be a proper application of
6 any methodology, including Bradford Hill's.

7 Q. So --

8 A. That's not what I did here in any sense.

9 Q. So just to be clear, you do not agree that the Bradford
10 Hill methodology requires a starting point with a null
11 hypothesis. Correct? That's your testimony?

12 A. My testimony is that in spirit, I think that it basically
13 does, but it's using an overly technical term in my opinion
14 that's incorrectly used in that context.

15 Q. Dr. Lagana, your certification explains that you took
16 into account the various categories of medical and scientific
17 literature and evidence discussed in your report.

18 And those -- the categories that you're referring to,
19 those are the citations that are listed at the end of your
20 paper. Correct?

21 A. At the end of my initial report?

22 Q. Yes.

23 A. Yes, yes.

24 Q. Now, your references cited did not include and 2021
25 article entitled "Permitted daily exposure limits for

1 noteworthy N-nitrosamines" by Dr. George Johnson, did it?

2 A. What is the date of publication on that article?

3 Q. It is April 2021.

4 A. April 2021.

5 Do you have the date of my...

6 When was my report filed? July 2021.

7 What is the citation again?

8 Q. The title of the article is "Permitted daily exposure
9 limits for the N-nitrosamines" that was written by Dr. George
10 Johnson. It's not on your citation list. Correct?

11 A. Allow me to review it. I don't recall.

12 No, I don't believe that I did rely on that study.

13 Q. And so you don't recall coming across Dr. Johnson's paper
14 when you did your literature review and research?

15 A. I don't recall, no.

16 Q. And so Dr. Johnson's paper did not factor into your
17 weight of the evidence analysis. Correct?

18 A. Nope, not if I didn't see it.

19 Q. And you were asked about this article in your deposition.

20 Have you not gone back to look at this article since you
21 were deposed?

22 A. I don't remember the questioning, and I did not go look
23 for the article.

24 Q. Well, I'll be glad to direct you to page 25 of your
25 deposition, if necessary, to refresh your recollection --

1 A. Okay.

2 Q. -- line 25.

3 And you were asked: Do you know Dr. Johnson, a
4 toxicologist, who came out with a recent article on NDMA and
5 NDEA?

6 And your answer was no.

7 Have you ever heard -- excuse me. You never heard of
8 him?

9 Not that I recall.

10 Did you read his article?

11 You said: We'd have to check the list.

12 And the question to you was: Sitting here right now, do
13 you have any recollection of reading Dr. Johnson's recent
14 article that came out in 2021?

15 And your answer was: I might recall the article. I
16 don't recall the name. I'd have to see what article we're
17 talking about.

18 Do you see that testimony?

19 A. Yes, yes.

20 Q. Okay.

21 A. I'd never read the article before or since, or I have no
22 recollection of having seen the article before or since.

23 Q. So did you not think that a recent 2021 article on
24 "Permitted daily exposure limits for noteworthy N-nitrosamines
25 found in valsartan" would be important to your opinions in

1 this case?

2 A. Well, certainly it'd be -- if I were to be called to
3 trial, it would be extremely important for me to fill in all
4 the -- to review all the literature that's been published from
5 the time when I drafted my report until the time that I was
6 going to speak to a jury. I don't think that I need to be
7 constantly monitoring it. I think it's -- I have not produced
8 a document with new opinions, so I have not -- I don't think
9 that it's necessary to talk about -- about my methods.

10 Looking at a new study is a new study. And I'd be happy to
11 deal with it and present it -- you know, present my opinions
12 to a jury on it should that become relevant. But that has
13 nothing to do with my methods that I took into -- that I used
14 to produce this report.

15 Q. Well, you understand that you're testifying here today
16 under oath in an MDL in federal court before a federal judge
17 to defend your methodology. And you didn't think that it was
18 important to go back and review the literature you'd relied
19 on?

20 A. I did review some of the literature I relied on. I
21 believe I just told you that the study that you're
22 highlighting is not one of the studies I relied on.

23 Q. Now, keeping in mind that there is a dearth of literature
24 published specifically on NDEA, wouldn't you want to see
25 Dr. Johnson's paper if it addresses NDEA?

1 A. Well, I have no knowledge of the paper, so it's hard for
2 me to speak to it, but I'd certainly -- if I were to be asked,
3 again, to opine about my general causation opinions, I would
4 review any literature that had been published in the time
5 between my production of the -- of my report and me delivering
6 my opinions again.

7 Q. Well, you were made familiar with the paper when you were
8 asked about it in your deposition last year. Correct?

9 A. It was mentioned to me. I was questioned for nine hours.
10 I'm sorry, I don't, you know, go home and start poring through
11 PubMed.

12 Q. Now, shifting gears for a moment, you -- in your
13 literature citations, you also cite to the WHO document.
14 Correct? That's another document you relied upon?

15 A. Yeah. There were several. I believe there was more than
16 one WHO citation, but, yes, the WHO's comments did inform my
17 thinking, along with the rest of the medical and scientific
18 literature.

19 Q. Well, and one of the bases for the WHO's conclusion about
20 carcinogenicity of nitrosamines according to your report was
21 the direct interaction with DNA consistent with tumor
22 formation.

23 Do you recall that from the WHO?

24 A. If you could just point out the part of my report that
25 you're referencing, I'd like to look it over for myself.

1 Q. Sure. It's page 12 and note 18, right in the middle of
2 the page.

3 A. Uh-huh.

4 Q. So in your report, you're talking about the World Health
5 Organization issuing a summary analysis. Right?

6 A. Correct.

7 Q. And you go on to talk about what the authors observed,
8 and you quote from the WHO: "Putative pathways for the
9 metabolism of" DNMA -- excuse me -- "NDMA are similar in
10 rodents and humans, and indeed the formation of the
11 06-methylguanine have been detected in human tissues exposed
12 to NDMA." They concluded, "Therefore, owing to the
13 considerable evidence of carcinogenicity in NDMA in laboratory
14 species, and evidence of direct interaction with DNA
15 consistent with tumor formation..."

16 That's the reference I'm directing you to. Do you see
17 that?

18 A. Yes.

19 Q. So my question to you is, did you in your literature
20 review take into account categories of medical and scientific
21 literature addressing the impact of DNA --

22 A. Sorry, there was a ding there.

23 Addressing what?

24 Q. I'll repeat it.

25 My question to you is, when you did your literature

1 review, did you take into account categories of medical and
2 scientific literature addressing the impact of DNA repair?

3 A. Absolutely. Yes. I have a rather lengthy section about
4 Lynch syndrome, which is a congenital deficiency of DNA
5 repair. So, yes, I did -- I did indeed think of DNA repair.

6 Q. Other than your reference to Lynch syndrome in your
7 discussion of the Danish study that you cite in your report --
8 other than discussion of Lynch syndrome, there's nowhere else
9 in your report that you considered or discussed the DNA
10 repair. Correct?

11 A. Certainly not true. I considered it. It's pathobiology
12 of cancer. You can -- I considered it throughout the drafting
13 of the entirety of the report. DNA can be injured by various
14 substances, including nitrosamines. And oftentimes that
15 insults or that injury is repaired, and sometimes it's not.
16 And when it's not, then you get a tumor. So that's just
17 pathobiology. And I did discuss it, that pathobiology, in
18 detail in the section about Lynch syndrome.

19 So to say, you know, I didn't think about it and didn't
20 write about it is totally inaccurate. I did think about it
21 and included it in my report.

22 Q. Well, my question is not did you think about it, but did
23 you actually look into the research on DNA repair?

24 A. Well, your question was did I consider it. You used the
25 words "did I consider it?" And I absolutely considered it.

1 As far as did I look into the research on DNA repair, to
2 an extent. And I quoted -- I cited it in the context of Lynch
3 syndrome. But also, it's background knowledge that I have
4 that I know well. It's part of my training.

5 Q. Okay. So in rendering your opinion, you didn't think
6 that it was necessary to do any literature review with respect
7 to DNA repair mechanisms then. Is that fair? You just relied
8 on your background and training?

9 A. I believe I said pretty clearly at least twice that I did
10 cite literature related to this in the context of Lynch
11 syndrome.

12 Q. Outside of Lynch syndrome, did you do any research into
13 DNA repair mechanisms?

14 A. I mean, as I sit here today, except for the example in
15 which I did do it, I don't remember a second example.

16 Q. You agree that dose and length of exposure are reasonable
17 things to consider when testing the hypothesis. Correct?

18 MR. SLATER: Your Honor, again, I would object at
19 this point. I believe that counsel's gone so far beyond the
20 certification that at this point I would ask that counsel be
21 limited to the certification.

22 THE COURT: Sustained.

23 Let's focus, please, on the certification.

24 BY MS. LOCKARD:

25 Q. Well, your various categories of medical and scientific

1 literature that you took into account, as mentioned in
2 paragraph 5 of your certification, those categories did not
3 take into account specific literature regarding a
4 dose-response curve. Correct?

5 A. Completely incorrect.

6 Q. You did not look at specific literature addressing a
7 dose-response curve by each of the cancers alleged in this
8 case, did you?

9 THE COURT: Excuse me. Let me interrupt.

10 Counsel, paragraph 5 of the certification is a
11 continuation of his discussion of null hypothesis. It doesn't
12 open the door to all the questions you asked him at his
13 deposition and all the grounds that you submitted in your
14 motion. Let's move on to what's in the certification, please.

15 MS. LOCKARD: Okay. I understand, Your Honor. I
16 hear you.

17 BY MS. LOCKARD:

18 Q. In paragraph 6 of your certification, Dr. Lagana, you
19 provide the example that you briefly referenced earlier
20 regarding a patient with cancer who is a lifetime cigarette
21 smoker. In that case, one would have a high index of
22 suspicion and place cigarette smoking high on the differential
23 diagnosis.

24 Do you see that in your certification?

25 A. I do.

1 Q. When making such an assessment to place cigarette smoking
2 on the differential, wouldn't it be important to you to assess
3 the dose and duration of the smoking?

4 A. Yes. Well, I think I said -- hold on one second.

5 I believe I said a lifetime cigarette smoker in my
6 certification. So yes, that would include, obviously,
7 considerations of dose and duration.

8 Q. So the statement in your report recognizes that dose and
9 duration are important when you're deriving a differential
10 diagnosis for a particular patient as to the cause of their
11 cancer. Correct?

12 A. I don't think it's controversial to say that more
13 cigarette smoking throughout one's lifetime is more risk to
14 you than less. That's well established. And I do. I have no
15 argument with the idea that dose and duration are important
16 when looking at any carcinogen.

17 Q. You would agree that that's true for any carcinogen,
18 correct, that more of the carcinogen is bad, less is less bad.
19 Correct?

20 A. That's a very general way of putting it. I think that,
21 you know, there are -- for some carcinogens there are
22 threshold levels. I wouldn't want to -- generally, I agree
23 with what you just said.

24 Q. Wouldn't it also be important to consider the type of
25 cancer when presented with a cancer patient with a history of

1 smoking, to determine etiology?

2 A. Absolutely. I think I said lung cancer in this example
3 that I gave, or at least I hope I did. Yes. Cigarettes are
4 well known to cause cancers of the lung, they cause cancer of
5 the bladder, they cause cancer of the head and neck. There
6 are some cancers that they specifically have been shown not to
7 cause, such as mesothelioma, for example.

8 So yes, the specific cancers are relevant when
9 considering the impact of a carcinogen.

10 Q. Well, in fact in your statement in your certification you
11 don't specify lung cancer.

12 A. Okay. I should have.

13 Q. Okay. And just like in your report and conclusions, you
14 discuss the risk of cancer generally, but you don't specify
15 individualized risks for each of the cancers that are alleged
16 in the suit, do you?

17 A. I'm not sure I totally understand the question. I dealt
18 specifically with whatever cancers were specifically in the
19 literature, such as gastric cancer, colorectal cancer, brain
20 tumors, lung cancer, liver cancer, pancreatic cancer. These
21 are the ones that -- bladder cancer, kidney cancer, ureter
22 cancer. These are the ones that come to mind as having had
23 specific literature references -- oh, esophageal cancer of
24 course.

25 Q. But you didn't do a Bradford Hill analysis with respect

1 to each of these individual cancer types. Right?

2 A. Each of those cancer types went into my overall Bradford
3 Hill analysis.

4 Q. Right. But your overall analysis was applying the nine
5 viewpoints to the issue of cancer in general, not specific
6 cancers. In other words, you didn't take a body of literature
7 that related to liver cancer and apply the nine viewpoints
8 from Bradford Hill to that body. Right?

9 A. Well, one of the important mechanistic pieces of this was
10 entry into the bloodstream. And I did deal with that directly
11 in my report. When the carcinogen does get into the
12 bloodstream, it becomes quite plausible that it can cause
13 cancer in generally any organ that receives blood.

14 A counter-example, for instance, would be asbestos.
15 Asbestos is a terrible carcinogen. It causes cancers, well
16 established to cause cancers of the lung and pleura, but it
17 doesn't get into the blood. So no one's had, like, I don't
18 know, brain cancer because of asbestos. So --

19 Q. And the answer to my question, respectfully, Doctor, was
20 no, you did not do an independent Bradford Hill analysis for
21 each of the cancer types. Right?

22 A. Well, I considered the viewpoints and I considered the
23 weight of the evidence. I did not do a formalized Bradford
24 Hill recitation for every type of cancer that is likely to be
25 caused by contaminated valsartan.

1 Q. But you would agree there was some inconsistency in the
2 literature when you look at these individual cancer types in
3 terms of the findings from the reports. Right?

4 MR. SLATER: Your Honor, I would place the same
5 objection.

6 MS. LOCKARD: I'm wrapping up, Judge.

7 THE COURT: Let's get it done, please. Let's get
8 focus back on the certification, please. Thank you.

9 BY MS. LOCKARD:

10 Q. Dr. Lagana, in terms of your literature review and your
11 Bradford Hill analysis which you have described, you didn't
12 seek to do an individual analysis from the literature or the
13 various categories of literature mentioned in paragraph 5.
14 You didn't do that, did you?

15 A. I did apply a weight of evidence approach to the specific
16 cancers where I felt -- where I felt it was appropriate.

17 Q. And then in your conclusion, you lumped your conclusions
18 in your report into one statement regarding the risk of
19 cancer, the potential causation of cancer in general.
20 Correct?

21 A. What exactly are you referring to?

22 Q. Well, you didn't seek to determine if there were
23 different dose curves for each of the cancers. You didn't
24 provide any analysis of different latency periods for each of
25 the cancers. Correct?

1 A. I discussed dose curves when they were available. I
2 discussed latency in the few examples in which it was
3 available. Whether I applied -- discussed those concepts in
4 detail in every type of cancer, I don't recall. But certainly
5 if I was looking at an individual patient, those would be
6 things that I would take into account.

7 Q. Correct. But looking at individual types of cancers, you
8 didn't do that in your report?

9 A. That's not true. I mean, there are plenty of references
10 to dose within the report related to specific cancers.

11 Q. But you didn't do a Bradford Hill analysis taking into
12 account the literature on a cancer-by-cancer basis. Right?

13 A. I worked with the guidelines in mind. And I took a
14 weight of evidence approach with respect to each individual
15 cancer.

16 Q. So your opinion in this case is the same regarding
17 colorectal, gastric, bladder, blood, pancreatic, esophageal,
18 prostate, lung or kidney, in terms of the relative risk
19 presented?

20 A. No. I didn't say that.

21 Q. Well, where in your -- where in your expert report do you
22 make an effort to assess individualized cancer risks? It's
23 not in there, is it?

24 A. It's certainly in there. Absolutely. I reviewed the
25 literature, and in places -- and with respect to specific

1 cancers where there are ranges of increased risk, absolutely.
2 That's all over my report.

3 Q. Well, you discussed the literature in your report that
4 was part of your various categories of medical and scientific
5 literature review. And where the literature discussed a
6 particular cancer, you included some of that language. Right?

7 A. Yeah. Where the literature gave a relative risk, and
8 particularly when it equated it to a particular dose, I
9 absolutely included that discussion in my -- in my report as
10 much as I could.

11 Q. Well, in your final conclusion in the case, however,
12 after looking at that body of literature that did provide
13 information about individualized relative risks of various
14 cancer, instead of putting that information into your
15 conclusion, your overall conclusion was all have an increased
16 risk of cancer as a result, and as a general matter, without
17 reference to individual predispositions or concurrent risk
18 factors, further increasing the risk on a case-by-case basis,
19 the larger the contamination and/or dose and the longer used,
20 the higher the increased risk of cancer. Cancer generally.

21 Correct? That was your conclusion in your report?

22 A. Well, the conclusion at the end of the report doesn't
23 negate any other conclusions that were drawn throughout the
24 body of the report. It's one report.

25 And so if I looked at -- if we look at -- if we turn to

1 the page on colorectal cancer -- let me find that.

2 On page 13, for example, that's looking at a study of --
3 a dietary study with respect to colon cancer. And they found
4 that there was a 46 percent increased risk of rectal cancer
5 compared to -- in high consumers of NDMA compared to low
6 consumers. And they actually also were able to put together a
7 dose for that, which was 126 nanograms per day.

8 So in this example, we had both an odds ratio or an -- a
9 specific increased risk and a dose.

10 And as I go through the papers, you know, the next
11 paragraph also shows what the strength of the association was,
12 how much elevation and risk was there.

13 So, you know, these are -- these paragraphs, they
14 summarize the increased risk with respect to colorectal
15 cancer.

16 Then if you look at page 14, I get into stomach cancer
17 and do the same -- the same thing.

18 So the fact that on the conclusion page paragraph I don't
19 rehash everything that has been in the report prior to it is
20 in no way a disavowal or a negation of everything that went
21 into the remainder of the report.

22 Q. Well, just taking NDEA for an example, you identified
23 Thresher and Zheng as literature supporting your opinion that
24 NDEA in the amounts in the valsartan caused cancer.

25 How do those two articles, the only finding of a

1 statistical significance at all was with respect to pancreatic
2 cancer from NDEA. Correct?

3 MR. SLATER: Your Honor, once again, I'll object. I
4 think we actually addressed NDEA and Your Honor asked counsel
5 to move on. I feel like we're going back to an area that was
6 already moved on from.

7 MS. LOCKARD: Your Honor, I appreciate that. Those
8 are all the questions I have at this time.

9 THE COURT: Thank you.

10 Mr. Slater, did you want to ask any questions?

11 MR. SLATER: I have no questions, Your Honor.

12 THE COURT: All right. Why don't we take a
13 ten-minute break and we'll get set up for the next one. Okay?

14 MR. SLATER: Thank you very much.

15 MS. LOCKARD: Thank you.

16 THE COURT: Thank you, everybody.

17 (Recess at 10:57 a.m. until 11:08 a.m.)

18 THE COURT: Mr. Nigh, you ready? Mr. Trischler, you
19 ready?

20 MR. NIGH: Yes, Your Honor.

21 MR. TRISCHLER: Yes, Your Honor.

22 THE COURT: Let's get started. The witness is here,
23 I see.

24 THE WITNESS: Yes, Your Honor.

25 THE COURT: Dr. Panigrahy, how are you?

1 THE WITNESS: Good, good. Thank you.

2 THE COURT: Raise your hand. I'm going to put you
3 under oath.

4 DIPAK PANIGRAHY, MD, PLAINTIFFS' WITNESS, after
5 having affirmed, was examined and testified as follows:

6 THE COURT: Would you state your full name, please,
7 sir.

8 THE WITNESS: Dipak Panigrahy.

9 THE COURT: Thank you.

10 Mr. Trischler, you may begin, sir.

11 MR. TRISCHLER: Thank you, Your Honor.

12 Before I do, in the event that there are certain
13 exhibits that are made part of the record, does the Court have
14 a preference for purposes of this hearing as to how we
15 identify Panigrahy-A, B, C, or whatever method the Court
16 prefers?

17 THE COURT: Have you previously identified them at
18 depositions and do you want to keep the same system? It's up
19 to you.

20 MR. TRISCHLER: Some we may have, but I can't say for
21 certain. That's why -- whatever the Court's preference is.

22 THE COURT: Well, probably Panigrahy-1 through
23 whatever would work. Thank you, sir.

24 MR. TRISCHLER: All right. Then we'll proceed in
25 that fashion. Thank you, Your Honor.

1 May I begin?

2 THE COURT: Please do.

3 MR. TRISCHLER: Thank you.

4 DIRECT EXAMINATION

5 BY MR. TRISCHLER:

6 Q. Dr. Panigrahy, good morning.

7 A. Good morning, sir.

8 Q. In your supplemental declaration that is dated
9 February 24, 2022, you cite three articles that were published
10 by Gombar that deal with the pharmacokinetics of NDMA in
11 certain animal species. Is that true?

12 A. Yes.

13 Q. And for the record, a paper that's entitled
14 "Pharmacokinetics of NDMA in beagles," a 1987 paper; is that
15 right?

16 A. Yes.

17 Q. And I will have that paper marked as Panigrahy-1. All
18 right?

19 And then you have a second paper that you referenced
20 entitled "Pharmacokinetics of NDMA in swine," a 1988 paper; is
21 that correct?

22 A. Correct.

23 Q. And we'll mark that as Panigrahy Exhibit 2. Okay?

24 A. Thank you.

25 Q. And then there's a third paper that you cite to entitled

1 "Interspecies scaling of the pharmacokinetics of NDMA,"
2 published in 1990; is that correct?

3 A. Correct.

4 Q. And we'll have that marked as Panigrahy Exhibit 3.

5 Sir, in these three animal studies by Gombar, NDMA was
6 administered to these animals both intravenously and through
7 oral doses. Correct?

8 A. Correct.

9 Q. And many of the doses that were administered in Gombar's
10 animal studies were massively large. Would you agree?

11 A. I'm not sure. You'd have to clarify what you mean by
12 massively large.

13 Q. Well, let's take a look at it and see if we can maybe
14 define it with a little more precision then.

15 If we start with Panigrahy-1, the beagle study. All
16 right?

17 In that study, is it true that the dogs were given two
18 doses totalling 1.5 milligrams per kilogram of NDMA
19 intravenously? If you can look at the first page of the --
20 paragraph of the abstract to help you if you need to, sir.

21 A. Yes. IV administration was 0.5 milligram per kilogram
22 and 1 milligram per kilogram.

23 Q. Right. So the total IV dose was 1.5 milligrams per
24 kilogram. Correct?

25 A. No. These dogs were getting separate doses. So one set

1 of dogs got 0.5 mg per kg. And then a different set of dogs
2 got 1 mg per kg.

3 Q. Take a look at Table 1 of that study.

4 A. Oh, yeah. Sorry, you're right.

5 Q. Okay.

6 A. Yeah. For the total amount.

7 Q. So just to be clear, the dogs in the beagle study were
8 given intravenous doses totalling 1.5 milligrams per kilogram.
9 Correct?

10 A. Correct.

11 Q. And in addition to those intravenous doses, each of the
12 dogs in Gombar's study were given two oral doses totalling
13 6 milligrams per kilogram?

14 A. Yes.

15 MR. TRISCHLER: And I apologize, Your Honor, we
16 have a -- these exhibits were loaded into a portal, and I
17 don't know if they have been made available to you and to
18 others, but there should be a way to access them. And I
19 apologize for not pointing that out a little bit --

20 THE COURT: I think they're attached to his
21 declaration.

22 MR. TRISCHLER: These ones are, yes. Yes, Your
23 Honor.

24 THE COURT: Okay.

25 MR. TRISCHLER: But there may be other exhibits that

1 I reference that are not attached, so I just wanted to let you
2 and Mr. Nigh and others know that there is a method to access
3 them as we identify them.

4 BY MR. TRISCHLER:

5 Q. But in any event, I apologize for digressing there,
6 Dr. Panigrahy.

7 But what I think we were getting at in walking through
8 the methods of this dog study was that a total dose of
9 7.5 milligrams for every kilogram was administered to the dogs
10 in the 1987 paper we've marked as Exhibit Number 1. Right?

11 A. Well, just to clarify, the total dose at one time was --
12 for orally was 1 mg per kg and then a different time was 5 mg
13 per kg.

14 Q. Yes, we've already covered that. But the total amount of
15 NDMA administered to these dogs in this study was
16 7.5 milligrams per kilogram?

17 A. Correct.

18 Q. Okay. And if we convert that to nanograms, we're talking
19 about a total dose of 7,500,000 nanograms per kilogram being
20 given to these dogs?

21 A. Correct.

22 Q. And would you agree with me that the average beagle
23 weighs about 10 kilograms?

24 A. Yes.

25 Q. All right. And so if we factor in the total weight of

1 the animal, these dogs received a dose of NDMA totaling
2 75 million nanograms as part of this study. True?

3 A. Correct.

4 Q. Do you know over what period of time this 75 million
5 nanogram dose was given to these dogs?

6 A. The study -- I believe it was over a month. They took a
7 two-week break between each of the IV dose and the oral dose.

8 Q. Can you show me where in the Exhibit 1 the time between
9 doses is discussed?

10 A. Yeah. Just looking at the Method section -- sorry.

11 Q. If you don't know or can't find it, I can move on for the
12 sake of time, Doctor.

13 A. Yeah. I believe they say somewhere in their paper they
14 waited about two weeks between the IV and the PO.

15 Q. But whatever the time period, whether it was two weeks, a
16 month, two days, whatever the case may be, over that period of
17 time, each of the beagles in the study received 75 million
18 nanograms of NDMA. True?

19 A. Correct.

20 Q. Can we agree, Dr. Panigrahy, that there's no plaintiff in
21 this litigation that ever ingested doses of
22 valsartan-containing medications having anything close to 75
23 million nanograms of NDMA?

24 A. So when converting -- for the mechanism of action for
25 NDMA, we don't use body weight from animals to humans. So

1 bioavailability, which is what this paper talks about, its
2 entire definition of area under the curve oral versus
3 intravenous, it's the amount of drug that will get into --
4 that gets into the systemic circulation. It's not -- doesn't
5 take into account the weight of the animal.

6 So there are two concepts here. One is the
7 bioavailability, which is what they're studying, which by
8 definition is the oral NDMA area under the curve divided by
9 the intravenous. And that doesn't -- the amount of NDMA --
10 actually, these doses in the dogs, 1 milligram per kilogram,
11 IV 0.5 mg per kg IV in the oral --

12 (Court reporter clarification.)

13 THE WITNESS: Oh, sorry.

14 Yeah. The 1 mg per kg IV and the 1 mg per kg and 5
15 mg per kg orally are actually in a dog quite low.

16 We do animal experiments in multiple species, in
17 rabbits, in goats, in mice, and that 1 mg per kg, many people
18 in the field would call that low.

19 But the mechanism of action of the cancer causation
20 is independent of the body weight going from animals to
21 humans.

22 BY MR. TRISCHLER:

23 Q. Doctor, respectfully, I didn't ask anything about
24 mechanism of the action or what was an appropriate dose for a
25 dog or bioavailability. I simply asked you if there's any

1 plaintiff in this action who ever ingested doses of
2 valsartan-containing medications having anything close to 75
3 million nanograms of NDMA?

4 A. No.

5 Q. In fact, in your work in this case, you had an
6 opportunity to review data and levels that were seen in the
7 valsartan-containing medications. True?

8 A. Correct.

9 Q. And you report on that at page 10, and I think maybe
10 page -- primarily on page 10 of your report. Correct?

11 A. Yes.

12 Q. And you -- for instance, you cite that Mylan's levels of
13 NDMA were found to be in the range of .01 to .09 parts per
14 million?

15 A. Correct.

16 Q. Do you remember that?

17 A. Yes.

18 Q. And if we use a dose of 320 milligrams, which is the
19 highest dose any patient could have ever received, that high
20 and low range translates to an NDMA level of between 3 and
21 28 nanograms per day. Correct?

22 A. Correct.

23 Q. And so let's say someone took NDMA in Mylan's valsartan
24 every day for four years. The total NDMA load on -- from the
25 low side to the high side over four years would be between

1 4,300 nanograms to 40,000 nanograms.

2 Can we agree on that math?

3 A. Correct.

4 Q. And on the other end of the spectrum, if we look at
5 another party to this case, ZHP, and on page 10 of your
6 report, you note that depending on the process that ZHP used,
7 their NDMA levels were observed to range anywhere from not
8 detected to 188.1 parts per million.

9 Do you remember writing that?

10 A. Yes.

11 Q. And the midpoint of that range is 94.05 parts per
12 million. Do you agree with that?

13 A. Yes.

14 Q. And then a 320 milligram tablet, using that midpoint of
15 94.05 parts per million, that's approximately 30,000 nanograms
16 of NDMA. True?

17 A. Correct.

18 Q. And so if someone were to take ZHP's valsartan for four
19 years, and we use that midpoint level for the NDMA content,
20 the total nanogram exposure of taking that drug every day for
21 four years at midpoint exposure gets you around 43 million
22 nanograms ingested over that four years. Would you agree with
23 that?

24 A. Yes.

25 Q. So after four years of taking valsartan at those levels,

1 we're still almost half or a little less than half -- a little
2 more than half of what the dogs received in this one Gombar
3 study that you cite in your supplemental declaration. Right?

4 A. We're mixing two concepts here. The important part, as I
5 wrote in my report, is that the levels of the NDMA in the
6 contaminated valsartan are about on the average 200-fold
7 higher than the levels that the FDA allows, than the 96
8 nanogram per day for NDMA.

9 And then in the dog study, which is bioavailability, the
10 weight of the animal is irrelevant. By definition,
11 bioavailability is the amount of drugs that is -- that is not
12 metabolized by the liver and goes into the circulation. The
13 Gombar studies address what is the bioavailability -- what is
14 the amount of NDMA that gets into the systemic circulation --

15 THE COURT: Doctor, excuse me. Please stop shuffling
16 your papers. We can't hear a word you're saying when you're
17 shuffling your papers, please.

18 THE WITNESS: Sorry.

19 THE COURT: Thank you. That's okay.

20 THE WITNESS: So the body weight of the -- the amount
21 of NDMA that is given to the dog is not relevant to the amount
22 of NDMA that I -- in my report, I calculate the amount of NDMA
23 in these contaminated tablets, which was on the average about
24 200-fold higher than the amount the FDA allows.

25 BY MR. TRISCHLER:

1 Q. Let me ask you about the swine study, which I think we've
2 marked as Exhibit 2.

3 Do you have that one in front of you?

4 A. Yes, sir.

5 Q. Good. In this study, the swine were, again, dosed both
6 orally and intravenously. Correct?

7 A. Correct.

8 Q. And the oral doses were 1.0 milligrams per kilogram and
9 5.0 milligrams per kilogram?

10 A. Correct.

11 Q. And according to this paper, if we look at page 1351, the
12 first page of Exhibit 2, down in the Materials and Methods
13 section, the average swine in this study weighted between 38
14 and 42 kilograms. Correct?

15 A. Correct.

16 Q. So we can use 40 kilograms as an average. You with me?

17 A. Yes.

18 Q. And just looking at the oral dose then, setting aside the
19 intravenous dose for the time period, let's just talk about
20 the oral dose, what this paper tells us is that the swine in
21 Gombar's study received an oral NDMA dose of 40 milligrams
22 followed by a second dose of 200 milligrams. True?

23 A. Sorry. I'm following -- the oral dose for a pig 9 to 11
24 is 1 mg per kg orally, and then pigs 12 to 14 were given 5 mg
25 per kg.

1 Q. Okay. So some received 40 milligrams and some received
2 200 milligrams?

3 A. Yes.

4 Q. And talk about -- and when you do that inversion to
5 nanograms, what's that? 200 million?

6 A. Sorry, I'm not following you.

7 Q. 200 milligrams is -- equals 200 million nanograms?

8 A. Right, right.

9 Q. So the doses of NDMA that were administered to the swine
10 in this Gombard study or Gombar study were even higher than
11 the doses in the beagle study?

12 A. Correct.

13 Q. And at the risk of stating the obvious, the Gombar papers
14 involve administration of NDMA to animals at doses that are
15 hundreds, thousands of times higher than the doses we're
16 dealing with in this litigation. Agreed?

17 A. No, I don't agree, because they're mixing two different
18 concepts. The doses that we give the animals to measure
19 bioavailability is different from the amount of doses in the
20 contaminated valsartan tablets.

21 Q. I agree it's different than the doses in the tablets.
22 That's my point.

23 And you've already told us that there's no plaintiff in
24 this litigation that ever ingested valsartan doses having
25 anything close to 75 million nanograms, and so it only

1 logically follows that there's no plaintiff in this litigation
2 that ever ingested valsartan-containing medications having
3 anything close to 200 million nanograms?

4 A. So for the case of genotoxic mutagenic chemicals that are
5 highly carcinogenic such as NDMA and NDEA, where the mechanism
6 of action is similar in animals and humans, IARC, WHO, many
7 agencies have said it's inappropriate to convert any type of
8 animal weight to human weight, because the mechanism of action
9 is through a metabolic activation through an ion.

10 So the weight of the beagle or the weight of the swine
11 isn't relevant in this case to the amount of NDMA that's in
12 the contaminated valsartan. What is relevant is the amount of
13 contaminated NDMA, that level compared to the level that the
14 FDA allows. And in my report, I carefully went through each
15 of the amounts of NDMA in the contaminated tablets. And on an
16 average it was around 187 to 200-fold increase over the FDA
17 levels.

18 Q. You've said that, sir. And none of that was responsive
19 to my question, respectfully. My only question to you was,
20 isn't it true that no one -- no plaintiff in this case was --
21 took a valsartan-containing medication containing 200 million
22 nanograms NDMA, yes or no?

23 A. Correct. But as I said, it's inappropriate to compare
24 the amount of NDMA -- or the body weight of the animal
25 compared to in the human, the amount of NDMA in the tablet.

1 Q. Doctor, if I could step back for a minute.

2 Are you familiar with the phrase "the dose makes the
3 poison"?

4 A. Yes.

5 Q. Do you agree with that fundamental concept?

6 A. Yes.

7 Q. Do you agree that dose matters when we evaluate the
8 toxicological and carcinogenic effects of a compound?

9 A. In general, the dose matters; but in the context of a
10 genotoxic versus nongenotoxic, it depends on the type of
11 carcinogen in this case.

12 Q. The dose matters whether you're talking about a genotoxic
13 or nongenotoxic compound. Water is vital to sustain life, but
14 if you take it in large enough doses, it can kill you. Right?

15 A. Right. But in a genotoxic mutagenic carcinogen as NDMA
16 and NDEA, there's no threshold with the dose. There's no --
17 the FDA has established an acceptable index, but when --
18 that's where we have to separate genotoxic mutagenic chemicals
19 versus non-genotoxic chemicals.

20 Q. When you say there's no threshold, what you're talking
21 about is that there's no regulatory agency that has
22 established a threshold, saying if you exceed that level, you
23 will sustain cancer or you will sustain certain types of human
24 cancers. That's what you're referring to. Correct?

25 MR. NIGH: If I may at this point, our certification

1 is on bioavailability, saturation and first pass metabolism.
2 This gets way outside of -- there's numerous pages dedicated
3 to dose. They've had ample opportunity to cross-examine him
4 in deposition. That is not the scope of his declaration.
5 It's bioavailability, saturation, and first pass metabolism.

6 THE COURT: Mr. Trischler, let's move on. Let's
7 concentrate, please, on the certification/declaration.

8 MR. TRISCHLER: If I may, Your Honor, I think my last
9 question was following up on the witness's answer, which I
10 would think I would be entitled to do.

11 If I could just make perhaps a larger proffer, the --
12 it's the defendants' position that those matters, those matter
13 to carcinogenicity, those matters to bioavailability, and in
14 his declaration and in the -- that this witness has submitted,
15 I submit that he ignores the significance of those since
16 Daubert requires an analysis of whether the expert reliably
17 applied science to the facts at hand.

18 I think that the marked differences in doses between
19 studies and the facts in this case need to be exposed and
20 explored. And that's what I'm trying to do. And I think
21 that's entirely relevant to inquiry whether the methodology
22 has been reliably applied to the facts at hand, which is part
23 of the -- I respectfully believe, the Daubert analysis. So I
24 think this is entirely relevant, appropriate.

25 MR. NIGH: Your Honor, may I respond?

1 THE COURT: I don't need it.

2 Mr. Trischler, were you able to ask during the
3 deposition of this witness about dose?

4 MR. TRISCHLER: Yes, sir.

5 THE COURT: And in your motion, the NDEA motion, you
6 raised the issue of exposure levels, don't you?

7 MR. TRISCHLER: I don't have the motion committed to
8 memory, but I would certainly hope so, Your Honor.

9 THE COURT: So I think we've plowed this ground a few
10 times. So let's move on, please. Thank you.

11 BY MR. TRISCHLER:

12 Q. One of the claims, Dr. Panigrahy, that has been made in
13 this case by plaintiffs is that exposure to NDMA is capable of
14 causing multiple cancers. Are you aware of that fact?

15 A. Yes, correct.

16 Q. And I have -- the plaintiffs have filed a disclosure of
17 cancer types at issue.

18 Have you seen that document before?

19 A. I'm not sure what you're referring to.

20 Q. Perhaps -- I don't know if the technician has that
21 document. It was sent to the portal. It's the plaintiffs'
22 disclosure and designation of expert types. It might have
23 been premarked as H. If we can mark it as Exhibit 4.

24 MR. NIGH: Judge, I can't see this document yet, but
25 I have a pretty good idea what's being referred to. It's a

1 certification made by plaintiffs' counsel as to the various
2 cancer types that they expect that experts may file expert
3 reports on. I think this is irrelevant and outside the scope
4 of Dr. Panigrahy's expert report. He has specific cancers
5 that he opines on that are related. Whether or not it's in a
6 certification is irrelevant by plaintiffs' lawyers.

7 THE COURT: Mr. Trischler, I don't have the document.
8 And I don't know who you're referring to about a technician
9 loading it into the system.

10 But what does this have to do with what he wrote in
11 his report or his declaration?

12 MR. TRISCHLER: It's really simply a predicate for
13 the question, Your Honor. I'm just trying to establish
14 that -- that he's aware of the fact that allegation has been
15 made that there were -- that NDMA exposure can cause cancer
16 types downstream of the liver. That's really all I'm trying
17 to establish by it.

18 I can do it without --

19 THE COURT: I'm sure he can answer that question,
20 whether he's aware that the downstream cancer types are being
21 alleged in this case.

22 MR. TRISCHLER: Right. That's all I was trying to
23 do, perhaps inartfully through the document.

24 THE WITNESS: Sorry, yes. In my report I detail ten
25 tumor types where I go into detailed -- actually Bradford Hill

1 criteria and nine different criteria of ten different tumor
2 types, in addition to liver, nine other tumor types.

3 BY MR. TRISCHLER:

4 Q. Based on your supplemental declaration, it's obvious to
5 me that you read the reports of defendants' expert and the
6 Daubert challenges that have been filed.

7 And do you understand that it's the defendants' position
8 that NDMA cannot cause cancers in downstream organs because of
9 the ingested NDMA cannot escape first pass metabolism in the
10 liver? Do you understand that to be the defendants' position?

11 A. Correct.

12 Q. And you disagree with that premise, as I understand it,
13 and you cite the Gombar papers in support of that position in
14 the supplemental declaration. Right?

15 A. Right. And also in my original report, of the 255-page
16 report, page 77 to page 80, four pages are dedicated solely to
17 the importance of bioavailability, which is studied in these
18 Gombar papers.

19 Q. But Gombar recognizes that dose matters when evaluating
20 the ability of the NDMA to escape the liver. Right?

21 A. Yes. In my report I have sections with five, ten pages
22 at a time where NDMA and NDEA have dose responses. I cited 32
23 publications just on the liver cancer section alone, 32 papers
24 where at least 10 have a dose response.

25 In science, you have to put it in context. So in the 580

1 papers I cite, if you're talking about a dose response, NDMA,
2 NDEA do exhibit dose responses in multiple tumor types, not
3 just liver cancer, lung cancer.

4 So dose does matter in -- it depends on the context.

5 Q. In the beagle study that we marked as Exhibit Number 1,
6 Gombar commented on rat studies, and he observed that -- of
7 what was classified as low doses resulted primarily in liver
8 tumors, but high-dose administration of NDMA resulted in renal
9 tumors. Isn't at that true?

10 A. Yes.

11 Q. And Gombar theorized that the low doses -- that at low
12 doses, little NDMA escapes the liver, but at high doses, the
13 liver can become saturated and a larger fraction of the dose
14 can reach systemic circulation.

15 A. Right.

16 Q. Do you recall reading that in Exhibit 1?

17 A. Yes.

18 Q. And again, the dose at which saturation was observed to
19 occur in Gombar in the beagle study was a single oral dose of
20 5 kilograms, which in the beagle we know to be 50 million
21 nanograms. Right?

22 A. Correct.

23 Q. Gombar never predicted that saturation occurs below a 50
24 million nanogram exposure, did he?

25 A. Well, Gombar did study this. At the 1 mg per kg there

1 was no saturation and they calculated the bioavailability to
2 be 93 percent.

3 Q. Right. So I guess I asked the question in a different
4 way than you answered it, but I think we arrived at the same
5 point. And that is, the only time in the beagle study that
6 Gombar observed any liver saturation was at the 550 million
7 nanogram dose?

8 A. Yes. The 5 mg per kg oral dose.

9 Q. And Gombar also reported in this study that DNA repair
10 enzymes in the liver of humans were likely to be more than
11 sufficient to prevent cancer from low-dose exposures. Isn't
12 that true?

13 A. I would have to see where -- where you're referring to.

14 Q. Can you look at page 346 of Exhibit 1, please.

15 A. Yes.

16 Q. Gombar writes: If humans are exposed to NDMA through
17 environmental exposure, not deliberate poisoning, the dose
18 will be exceedingly low. Based on rat data, it would be
19 expected that a very small fraction of the dose would pass
20 through the liver. The ability of the human liver to repair a
21 lesion such as O-methylguanine should be sufficient to
22 substantially reduce the risk of liver cancer from this type
23 of exposure. Correct?

24 A. Right. They're citing a paper, reference 36.

25 Q. Right. And there's nothing in Gombar's beagle study that

1 suggests that liver saturation is going to occur at doses as
2 low as 150 nanograms, is it? Is there?

3 A. Sorry, I didn't follow the question.

4 Q. I apologize if it wasn't clear.

5 What I was asking is, there's nothing in Gombar's beagle
6 study that would suggest or support the proposition that liver
7 saturation in the human is going to occur at doses like 150
8 nanograms or a 1,000 nanograms or even 10,000 nanograms?

9 A. So by definition, bioavailability is -- doesn't calculate
10 saturation. There are two different concepts that are being
11 mixed here.

12 Bioavailability by definition is just the amount of NDMA
13 that gets past the liver unmetabolized and gets into the
14 systemic blood flow and can cause cancer throughout the body.

15 Q. All right. Well, that's -- that's fine. But it wasn't,
16 respectfully, responsive to my question.

17 I think what I asked you was, the only time -- I asked
18 you about saturation, not bioavailability. I think I
19 understand that there's a difference.

20 And the only time Gombar observed saturation was at the
21 high dose of 5 milligrams per kilogram. Correct?

22 A. Correct.

23 Q. So there's nothing in Gombar's study that you brought to
24 the attention to the Court in your supplemental declaration to
25 suggest that the human liver becomes saturated if it receives

1 a dose of NDMA of 1,000 nanograms or 10,000 nanograms or even
2 100,000 nanograms. True?

3 A. It's not relevant here. The saturation at the high dose
4 actually has higher bioavailability. What Gombar has studied
5 at the 1 mg per kg dose where they calculated 93 percent
6 bioavailability, there was no saturation.

7 Bioavailability is independent of the saturation. By
8 definition, it's -- I won't go into it's area under the curve,
9 it's just when you give the NDMA orally versus when you give
10 it intravenously, which by definition, you get 100 percent.
11 Saturation is just the amount of extent a chemical can be
12 either solubilized or permeabilized. Saturation is a
13 different definition from bioavailability. Gombar was
14 addressing what the bioavailability is here.

15 MR. TRISCHLER: Your Honor, I'm going to object and
16 move to strike as nonresponsive. I don't think I've gotten an
17 answer to the question of whether there's anything in this
18 paper that would allow a research scientist to conclude that
19 the human liver becomes saturated at doses of NDMA below
20 100,000 nanograms.

21 MR. NIGH: Your Honor, if I may, our certification
22 never says that we need to have saturation in order for NDMA
23 to get past the liver. Our certification is clear that all it
24 takes is bioavailability, even without saturation. That's his
25 opinion. 49 to 93 percent gets past the liver without

1 saturation. That's what we're trying to make clear in the
2 declaration. And Mr. Trischler keeps going on to when it's
3 going to be saturated and how much does it take to be
4 saturated. That's not his declaration opinion. 49 to
5 93 percent gets past the liver without saturation.

6 THE COURT: Well, clearly he's trying to say that
7 saturation is irrelevant to the amount of NDMA that enters the
8 human bloodstream. But to Mr. Trischler's point, that whether
9 or not this Gombar study means that human livers can be
10 saturated at the low levels, the relatively low levels,
11 relative to these animals, of NDMA ingestion is his precise
12 question.

13 I agree that it doesn't have a whole lot of
14 relevance, but that's his question, and the witness hasn't
15 answered that yet.

16 Doctor, can you answer the question about saturation
17 of human livers and whether you can take anything from the
18 Gombar study regarding saturation? I understand your point
19 about bioavailability, but the question's about saturation.

20 THE WITNESS: Oh, sorry. I missed the -- so, yes, we
21 cannot -- in the -- we can't conclude from the 1987, this
22 particular study, what amount in the human would saturate the
23 liver.

24 But what we can conclude, if we jump to the -- I
25 think this is where you're getting at is what would be the

1 bioavailability in humans, what would be -- and that's
2 addressed in the 1990 Gombar paper I cited.

3 THE COURT: Well, that's not what Mr. Trischler is
4 getting at at the moment. He's focusing on saturation. I
5 understand your point, though, about bioavailability, but
6 let's just focus on what Mr. Trischler is asking, which is
7 about saturation at this time. Okay?

8 Thank you.

9 THE WITNESS: Sorry, just to clarify the question
10 again. I missed it.

11 MR. TRISCHLER: I'll reask it.

12 THE COURT: Please.

13 BY MR. TRISCHLER:

14 Q. There is no -- nothing in the beagle study that would
15 support a conclusion that the human liver becomes saturated at
16 relatively low levels of NDMA exposure on the order of 10,000
17 to 100,000 nanograms, is there?

18 A. Correct.

19 Q. Now, are you familiar with the work of Professor Maria
20 Diaz Gomez on the pharmacokinetics of NDMA?

21 A. Yes. I did -- you know, I cited one paper with -- she
22 was a co-author, and there's several papers. I'm not sure
23 which one.

24 Q. Well, I was referring to the papers that Gombar cites to
25 that we've marked as Exhibits 1, 2 and 3.

1 Have you read the papers of hers that are cited by Gombar
2 in his work?

3 A. Yes. There's several papers. I have the one, actually,
4 right in front of me. 1977?

5 Q. I think so.

6 A. Yeah. Yep.

7 Q. Okay. And isn't it true that Dr. Gomez reported that
8 when orally administered, liver prevents nitrosamines from
9 reaching other organs?

10 A. Yes. And this is consistent with my report where low
11 doses can get metabolized by the liver, and at higher doses,
12 the NDMA gets past the liver and you can get other cancer
13 types.

14 Q. And so far in the papers that we've talked about, the
15 high doses getting past the liver have been defined as -- by
16 Gombar as 5 milligrams per kilogram. Correct?

17 A. No. The 1 mg per kg, the low oral dose, is what they
18 used to calculate the bioavailability, not the 5 mg per kg.
19 And at that low dose, there's no saturation. And the
20 bioavailability in the dogs was 93 percent, you know, swine,
21 67 percent.

22 Q. In the Diaz Gomez paper that you read and that Gombar
23 cites to, the scientists in that paper write that: These
24 experiments would imply that in a healthy man, the metabolism
25 and activation of NDMA in the diet would take place in the

1 liver, and that the liver would remove the nitrosamine from
2 the portal blood and prevent it from reaching other organs.

3 Do you agree with that?

4 A. I'm sorry. I'm just getting to -- what page?

5 Q. 499, sir.

6 A. Yes. Which paragraph?

7 Q. It's in the bottom right-hand column, last paragraph.

8 A. Yes. I see it.

9 Q. Do you agree with that statement, sir?

10 A. That can happen in a certain -- what I wrote in my report
11 is that -- so we don't rely on one paper. In certain papers,
12 NDMA can cause liver cancer, but in other papers, the NDMA can
13 cause kidney cancer and many other types. And that's -- by
14 definition, the NDMA is getting past the liver.

15 And in science, we don't rely on two, three papers. When
16 I cited all these papers and, for example, the Anderson paper,
17 which is a 1994, oral NDMA in a monkey caused DNA adducts in
18 32 different tissues. So that's an important finding, that in
19 a species that's similar to humans, that one single dose can
20 get past the liver and cause DNA adducts, which is one of the
21 initiators of the mechanism, how it causes cancer, in 32
22 different tissues.

23 So, yes, there are papers, and I do agree with the
24 sentence that at low doses in certain papers NDMA in a rodent
25 can cause liver cancer, but then I cite other papers where

1 NDMA in the mouse or the rat or rodent can cause other tumor
2 types, like kidney cancer.

3 In fact, this is an important point, that when a chemical
4 is multi-species, multi-organ by different administrations,
5 that's when -- and it's genotoxic, that's why this chemical
6 has been studied in hundreds of papers, which I cited. So we
7 don't rely on just one paper on this.

8 Q. Sir, I don't think -- somewhere in there, there might
9 have been an answer to my question, but if there was, I missed
10 it, so let me try again.

11 All I asked you is if you agree or disagree with this
12 statement, quote: If man and the rat are comparable, these
13 experiments would imply that in a healthy man, the metabolism
14 and activation of NDMA in the diet would take place in the
15 liver, and the liver would remove the nitrosamine from portal
16 blood and prevent it from reaching other organs.

17 That was the conclusion from Diaz Gomez.

18 Do you agree with it?

19 A. No, I don't. Because as I cite in my report, the NDMA
20 given in a rodent can cause other tumor types. If we only saw
21 one tumor type, I would agree with this comment that, yes, the
22 liver is the only organ that can metabolize NDMA, but we know
23 NDMA in rodents causes a -- and I wrote in my report at least
24 seven different type of tumor types that are beyond the liver.

25 So in discussions you can say anything you want in a

1 scientific paper. Usually peer reviews are more critical on
2 the data generation. So to back up a sentence like that, I
3 would have to see a peer-reviewed paper to support that.

4 Q. Did you also read the -- well, isn't Professor Diaz
5 Gomez's paper published in 1977 peer reviewed?

6 A. Yes, yes. No, but I --

7 Q. And her statement would have been peer reviewed?

8 A. Right. So where I say we don't rely on one paper in
9 science, like, for example, I gave -- I'll just give one paper
10 example, the Anderson paper that I cited, 1994, that an oral
11 administration of NDMA in the monkey, which is genetically
12 closer to a human, induced 32 different tissues to have DNA
13 adducts.

14 So by definition, when you get DNA adducts beyond the
15 liver, that's showing absorption and excretion and
16 bioavailability in an indirect way. The Gombar studies
17 bioavailability directly by measuring the concentration. But
18 there are indirect measures in science.

19 And so, yeah, that's where I say this one sentence, I
20 actually support -- certainly, papers that I cite in my report
21 do support that NDMA causes liver cancer. In fact, I cited 32
22 publications in the liver section part that NDMA causes liver
23 cancer. But you can't ignore the other papers that NDMA can
24 cause other types of cancers, like seven different types of
25 cancers in ten different species via six different

1 administration methods.

2 Q. I didn't -- sir, I didn't ask you about cancer causation.
3 All we're talking about is metabolism right now. I thought
4 you knew that.

5 But since you brought it up, this Anderson paper that
6 you've mentioned, can you give us a citation to that whole
7 paper, please?

8 A. Sure. It's actually reference 121 in my -- it's
9 reference 121 in my report on page 228.

10 Q. Okay. And what was the dose that was given to the
11 monkeys to induce cancer in that study?

12 A. Let's see. I have to -- I believe it was on the order of
13 1 mg per kg or 0.1 mg per kg.

14 Q. Well, why don't you take the time to look at it, because
15 I'd like an answer that we can rely on.

16 A. Sure.

17 THE COURT: While we're waiting, for the
18 court reporter, Ms. Mitchell, when the witness testified
19 adducts DNA, it's A-D-D-U-C-T-S, adducts. Okay?

20 THE TECHNICIAN: Good morning or good afternoon,
21 everyone, depending on where you are. This is James Budkins,
22 your concierge for today.

23 THE WITNESS: So the dose, adult monkeys received
24 0.1 mg per kg NDMA orally by gavage.

25 BY MR. TRISCHLER:

1 Q. And is this study called "NDMA derived O-methylguanine in
2 DNA of monkey gastrointestinal and urogenital organs and
3 enhancement by ethanol"?

4 A. Yes.

5 Q. That's a mouthful.

6 A. Yeah.

7 Q. Glad I was able to spit it out.

8 But in this study what was done was that alcohol was
9 administered to the monkeys in addition to NDMA in order to
10 defeat the DNA enzymes of that mammal. Correct? The DNA
11 repair enzymes of that mammal, I should say.

12 A. Correct. In some of the monkeys, they did receive
13 ethanol too.

14 Q. Right.

15 A. Yes.

16 Q. So going back to the issue that I wanted to talk about,
17 because I thought this is what your supplemental declaration
18 dealt with, where the Gombar papers and the materials that
19 were relied upon by Gombar to determine whether or not there's
20 a scientific basis to support this idea of -- about NDMA's
21 ability to cause cancer downstream of the liver. Are you with
22 me?

23 A. Yes.

24 Q. So we were talking about the Diaz Gomez paper.

25 Another paper that Gombar cites is the paper by Mico,

1 M-I-C-O. Do you remember reading that paper?

2 A. Yes.

3 Q. I think you also cited to that paper in your own report.

4 Correct?

5 A. Correct.

6 Q. And just like Diaz Gomez, Mico and his colleagues
7 reported in their study that the results support the previous
8 conclusion that the liver is the site of NDMA-induced lesions
9 after low chronic doses because it is the virtual -- it is
10 virtually the exclusive site of metabolism after oral
11 administration. Isn't that what Mico found?

12 A. Well, Mico did find that the bioavailability in the
13 rodents are in that 8 to 10 percent range. And that's what
14 Gombar does cite in the Gombar papers. And that's an
15 important concept, that in the animals with lower body weight,
16 the rodents, that the bioavailability was only in that 8 to
17 10 percent, and that in the higher animals, the swine, the
18 dog, the monkey, the bioavailability was almost 12-fold higher
19 than the rodents, even though all the species -- the seven
20 species they studied had very high clearance. So that's a
21 very important point. And this gets back to because
22 obviously -- because NDMA is a human carcinogen, we can't test
23 it in animal -- in humans.

24 And so the third paper that I cited for the declaration,
25 which we may get to, that's where they actually do cite the

1 Mico paper. And Figure 3 has an extrapolation between the
2 mouse, the hamster, the rat, and then the pig, the swine, and
3 the monkey.

4 And that -- that's where -- the bottom line, as I wrote
5 in the declaration, the larger animals have higher
6 bioavailability, up to 12-fold higher than the rodents.

7 And this would argue and suggest that NDMA in larger
8 species, including human, would have much more systemic
9 bioavailability of NDMA and it can get past the liver.

10 Q. Is a pig a good comparison to the human?

11 A. So I actually did cite in my report that a pig -- there
12 are a lot of advantages. The pig has a similar cardiovascular
13 system, similar immune system, similar physiology as humans.
14 So in certain ways, a pig would be better than a rodent.

15 Q. Okay. But let me focus on Mico for a minute.

16 Do you have that study?

17 A. Let me see. I can probably pull it up on my computer. I
18 don't have a printout.

19 MR. NIGH: Is this an exhibit that you're using?
20 Because he doesn't have this printed out. And if we're going
21 to use this as an exhibit, I'd like a copy of the exhibit as
22 well.

23 MR. TRISCHLER: Yes. I can mark it as Exhibit E,
24 Mr. Nigh, if you'd like. And there should be an ability to --
25 I don't know if our concierge has that ability, but there

1 should be an ability to display it.

2 THE WITNESS: I do have the paper on my computer.

3 BY MR. TRISCHLER:

4 Q. All right. Then in the interest of time to try to move
5 forward, if you have the paper in front of you --

6 MR. TRISCHLER: And I apologize, Mr. Nigh, that you
7 don't have it. If you want --

8 MR. NIGH: I would object. If we're using an
9 exhibit, he didn't print out 600 page -- you know, every
10 single exhibit in his expert report. If we're using it, I
11 believe I'm entitled to a copy.

12 MR. TRISCHLER: I don't disagree.

13 Your Honor, may we take a recess so I can figure out
14 how I can get the exhibit to Mr. Nigh? I'm not as proficient
15 with remote procedures as I should be.

16 THE COURT: Somebody came -- yes, the answer your
17 question, sure.

18 But somebody came on as a concierge.

19 Who set that up?

20 MR. TRISCHLER: I thought it was set up to assist in
21 providing the exhibits and presenting them.

22 THE COURT: We didn't. The Court didn't set that up,
23 so --

24 MR. TRISCHLER: We did. The defendants did.

25 THE COURT: Okay. Well, then why don't you get in

1 touch with your concierge and find out if we can get this
2 stuff up. We'll take a little break.

3 MR. TRISCHLER: May we take five minutes to figure
4 out some administrative issues?

5 THE COURT: Sure.

6 (Recess at 12:07 p.m. to 12:24 p.m.)

7 MR. NIGH: Can I raise my objection to showing the
8 Mico. The declaration clearly mentions the Gombar study
9 and the human -- I mean the pigs, the monkeys and the dogs
10 being the larger species, and Panigrahy's opinion being that
11 the bioavailability would be the similar to the larger
12 species, not the rodents. And I see that we're going to be
13 showing another rodent study. This is outside of his scope.
14 His opinion is based on larger species compared to -- in
15 larger species being similar to the human.

16 MR. TRISCHLER: The Mico study is cited by Gombar.
17 The witness has cited to 268 animal studies in his report,
18 over 150 of which involve rats and rodents. Considering that
19 this is a paper cited in -- cited by Gombar, I think it's
20 directly probative of the issues of bioavailability,
21 saturation and metabolism of NDMA.

22 THE COURT: I'm not familiar with the Mico study,
23 Mr. Trischler.

24 How about the Reader's Digest version of it. What
25 does the Mico study say in your estimation?

1 MR. TRISCHLER: Essentially what the Mico study says
2 is that at low doses, the liver is the site of metabolism of
3 NDMA and --

4 THE COURT: Why can't we ask the witness that
5 question, whether he agrees or not with that?

6 MR. TRISCHLER: That's what I was trying to do. I
7 was going to refer to a specific statement when we got
8 sidetracked by trying to find the document so that the witness
9 could see the statement that I was going to ask about. But --

10 THE COURT: Why don't you just read him the statement
11 and ask if he agrees or disagrees with it and what his reasons
12 are and we'll go with there. Why do we need to spend all this
13 time trying to find this thing?

14 MR. TRISCHLER: Very well, Your Honor.

15 MR. NIGH: Your Honor, there is over 90 to 100
16 different studies that are cited by Gombar and there's over
17 600 studies cited in his expert report. I don't think that's
18 a basis to say that's within the parameters of his
19 declaration. His declaration is much more limited than that.

20 THE COURT: It's a very limited declaration. It's
21 about saturation and bioavailability and how bioavailability
22 is not dependent on saturation. I get it. But I'm going to
23 let him ask this question about -- because we have talked
24 about the relative size of the animal and that effect on the
25 bioavailability of NDMA.

1 So go ahead, Mr. Trischler, ask your question.

2 MR. TRISCHLER: All right.

3 BY MR. TRISCHLER:

4 Q. Dr. Panigrahy, referring to the Mico study, do you agree
5 that the authors of the Mico paper concluded that at low doses
6 the liver is the site of metabolism of NDMA?

7 A. Yes.

8 Q. Have you -- now, have you read all of the work by Gombar
9 and his colleagues on the subject of the pharmacokinetics of
10 NDMA?

11 A. I've read the three Gombar papers, if you're asking, the
12 three papers that I cited in this declaration, so yes.

13 Q. Are you familiar with the paper by Harrington entitled
14 "The Formation, Disposition and Hepatic Metabolism of NDMA in
15 the Pig"?

16 A. Which reference are you -- I don't know that offhand.
17 Which reference are you...

18 Q. It's cited -- it's a paper by Harrington cited in the
19 Gombar papers that you have mentioned in your declaration.

20 A. Which of the three Gombar papers? And I can probably
21 find the reference.

22 Q. Let me show you the first page of the document and see if
23 it refreshes your recollection.

24 James, can you display that, please?

25 THE TECHNICIAN: Yes, no problem. This is J which

1 will be 5. Correct?

2 MR. TRISCHLER: 6, but --

3 THE TECHNICIAN: This is the Mico. Correct?

4 MR. TRISCHLER: 5 is Mico. This is Harrington.

5 THE TECHNICIAN: Harrington.

6 MR. NIGH: Judge, I would renew my objection. I
7 don't see how it's fair, even for foundational questions, to
8 show a document that's not being provided to the witness as a
9 whole copy or to Your Honor or to myself.

10 Judge, you're on mute.

11 THE COURT: Thank you.

12 Doctor, this is I think the swine study, and it's
13 note number 8 I think is the Harrington paper he's referring
14 to? I think. Harrington, McGee.

15 MR. TRISCHLER: Yes, Your Honor.

16 THE COURT: Can you see that, Doctor?

17 THE WITNESS: I see reference 8, yes.

18 THE COURT: Are you familiar with that paper?

19 THE WITNESS: Yeah. I think in the thousand
20 publications over that I reviewed, I did remember, you know,
21 this could have been one of them.

22 THE COURT: Okay.

23 BY MR. TRISCHLER:

24 Q. In Harrington, the lead author on this paper, Exhibit 6,
25 Harrington is actually one of the co-authors of the three

1 Gombar papers that we've been talking about. Correct?

2 A. Right.

3 Q. And if I can direct your attention to this paper, you've
4 already told us that the pig is a good model for the human.
5 If we look at page 627 of this paper, we see three graphs on
6 the bottom right side of the document.

7 MR. NIGH: Judge, now we're actually using the
8 document. I'm going to object to this because my witness
9 doesn't have a copy of the document. It sounds like we're
10 going to start selectively choosing a few phrases, and the
11 doctor doesn't have the context around it, neither do I, and I
12 don't believe Your Honor has it either.

13 MR. TRISCHLER: The doctor has already said he's read
14 it and he's familiar with it. If he needs time to review it,
15 we can provide him the time to review it. But I think it's
16 fair cross-examination of a paper by the same authors who
17 wrote the papers on which he's relying upon.

18 THE COURT: Mr. Trischler, what's the point? Where
19 are we going with this?

20 MR. TRISCHLER: The point, this paper, I believe,
21 contradicts his conclusions concerning the pharmacokinetics of
22 NDMA.

23 THE COURT: You have experts who directly contradict
24 his conclusions who cite other papers. So what? I'm aware of
25 that.

1 Unless you think you can get him to recant,
2 completely recant his declaration, there's no point to this.
3 It's not helping me at all.

4 MR. TRISCHLER: I want -- fine, Your Honor. If the
5 ruling is that I can't cross-examine on the document, I'll
6 respect the ruling.

7 THE COURT: Well, nobody has it. It's going to take
8 us hours apparently to get it and have everybody have an
9 opportunity to look at it.

10 So I'm going to sustain the objection. Let's move
11 on.

12 BY MR. TRISCHLER:

13 Q. You have embraced the -- Professor Gombar's work and
14 findings in these three papers that we have marked as
15 Panigrahy-1, -2 and -3. Fair to say?

16 A. Correct.

17 Q. And -- but given species to species differences, the
18 differences in doses between animal studies and humans and
19 other factors, do you agree that Professor Gombar and others
20 have repeatedly cautioned against using animal data like this
21 to extrapolate carcinogenicity to humans?

22 MR. NIGH: I'm going to object. This is going
23 outside the scope. Carcinogenicity is not bioavailability,
24 it's not saturation, it's not first metabolism. We're going
25 outside the scope again.

1 THE COURT: Mr. Trischler, what does this have to do
2 with saturation and bioavailability, which is the subject of
3 this declaration?

4 MR. TRISCHLER: It's right in the papers that he
5 cited that are in his declaration that --

6 THE COURT: Well, that's not -- first of all, that's
7 not what he cited the papers for.

8 Second of all, I've already addressed this on Monday.
9 I understand and we all understand and all scientists
10 understand the difficulties in extrapolating human studies --
11 I mean, animal studies to humans. That's a given. We all get
12 that. And it's got nothing to do with bioavailability and
13 saturation. Let's move on.

14 BY MR. TRISCHLER:

15 Q. You agree that Gombar has admitted it himself that proof
16 of NDMA as a human carcinogen is lacking?

17 MR. NIGH: Again, outside the scope.

18 THE COURT: Sustained.

19 MR. TRISCHLER: Your Honor, if I may make a proffer,
20 the doctrine of completeness, if a witness relies on a study,
21 you should be permitted to introduce evidence of other
22 relevant information in the same study that the witness is
23 relying upon.

24 THE COURT: Counsel, you're forgetting where you are.
25 This is not a jury. This is me trying to answer the questions

1 raised in your motions, the very, very limited role that I
2 have. This is not helping me decide your motions.

3 I understand that there's weaknesses in all the
4 reports. I understand -- and both sides have pointed them out
5 very well, which I tried to say the other day. I get all
6 that. This is not an opportunity to refile your motions,
7 reargue your motions. This is not a jury who is going to
8 determine who has got the better witnesses. This is not a
9 jury who is going to determine whether or not a particular
10 expert should or shouldn't have relied heavily on a particular
11 study. That's not what we're doing here.

12 Focus on the declaration, please. Thank you.

13 MR. TRISCHLER: Understanding the Court's ruling, I
14 have no further questions.

15 THE COURT: Mr. Nigh, any questions?

16 MR. NIGH: Briefly, Your Honor.

17 CROSS-EXAMINATION

18 BY MR. NIGH:

19 Q. Doctor, do you have your declaration in front of you?

20 A. Yes.

21 Q. And did you read page 11 of the defendants' reply brief
22 wherein they criticized your opinions because you did not
23 state the level of NDMA required to saturate the liver?

24 A. Yes.

25 Q. Doctor, can you explain what bioavailability means?

1 A. Yes. I defined it in the document number 4.

2 Bioavailability is the percentage of the NDMA dose that will
3 pass the liver without being metabolized and thereby be
4 available in the systemic circulation.

5 Q. Doctor, how does saturation relate to bioavailability?

6 A. Saturation is the -- by definition is the extent where
7 NDMA could be solubilized or permeabilized. The definition of
8 bioavailability is independent of saturation. So there are
9 two concepts that the defendants are conflicting --
10 conflating.

11 Q. Doctor, once the liver is fully saturated, what
12 percentage of the remaining dose becomes bioavailable?

13 A. Then 100 percent will become bioavailable.

14 Q. Doctor, does the liver need to be saturated before
15 bioavailability can occur?

16 A. No, it does not, and that's why I cited the three Gombar
17 papers. At the low oral dose, there's no saturation, yet
18 there's high bioavailability.

19 Q. And Doctor, does the liver need to be saturated before
20 some of the substance gets past or a percentage of the
21 substance gets past the liver?

22 A. No.

23 Q. Why not?

24 A. Because by definition, the systemic bioavailability is
25 the amount of the chemical, in this case NDMA, that gets into

1 the systemic circulation, and that's independent of that
2 saturation.

3 Q. And Doctor, specifically for NDMA, does the liver need to
4 be saturated for NDMA to get past the liver?

5 A. No.

6 Q. Why not?

7 A. Because the blood will flow -- you'll have a -- there's
8 no 0 percent bioavailability. Even in the rodent, which is 8
9 to 10 percent, a certain amount of the NDMA can get past the
10 liver. So the bioavailability -- again, I define it, it's the
11 amount of drug that gets past the liver. And that's, as I
12 said before, the area under the curve through the oral
13 delivery divided by the intravenous. It's just the definition
14 that's independent of saturation.

15 Q. Doctor, are there any studies that support the idea that
16 NDMA gets past the liver regardless of whether the liver is
17 saturated?

18 A. Yes. So the Gombar papers I cited, they clearly show at
19 the low oral dose, at the 1 mg per kg, there's no saturation.
20 And in the swine, there is 67 percent bioavailability. In the
21 dog -- beagle study was 93 percent, again, at the low oral
22 dose where there's no saturation. And then in the monkey,
23 there was 49 percent bioavailability, independent of the
24 saturation.

25 Q. So did the Gombar studies support that for the dog,

1 93 percent of the NDMA is getting past the liver and into the
2 bloodstream?

3 A. Yes.

4 Q. Doctor, and that's before saturation. Correct?

5 A. Right.

6 Q. If it were saturated, the liver -- then saturated a
7 higher amount gets past the liver than the 93 percent in the
8 dogs. Correct?

9 A. Correct. And that's what Gombar showed. Actually at the
10 higher doses where there was saturation at the 5 mg per kg
11 orally, the percent of bioavailability was even higher than
12 the 93 percent in the dog and the 67 percent in the swine.

13 Q. Doctor, did the Gombar study author suggest any
14 differences in the amount of NDMA that gets past the liver
15 between larger animals versus smaller animals?

16 A. Yes. These studies would suggest more NDMA would get in
17 the systemic circulation in a larger species such as the dog,
18 swine, and pig. And they suggest in their 1990 paper that a
19 human would be more like a larger species, so it would have
20 higher bioavailability than a rodent.

21 MR. NIGH: I don't have any further questions, Your
22 Honor.

23 THE COURT: Mr. Trischler, do you want to ask any
24 questions about that?

25 MR. TRISCHLER: No. Thank you, sir.

1 THE COURT: All right. Thank you.

2 All right. What's the status on the next witness?

3 Do we need to take a -- it's 12:43. Can we start, and then if
4 we have to break, because Ms. Brown needs to go? Do you want
5 to start, Ms. Brown, with the next witness?

6 MS. BROWN: I completely defer to the Court, Your
7 Honor, whatever is best. I was going to ask for a few minutes
8 with the tech person to just see if I can get my Elmo working
9 so I myself could show a document and save us trouble. But if
10 Your Honor's preference is to just keep going, we can do that
11 too.

12 THE COURT: Well, let's take a 10-minute break and
13 then try to get set up and get the witness --

14 MS. BROWN: I appreciate it.

15 THE COURT: -- who's somewhere far away, I think I
16 remember. So let's get the witness. We'll take ten minutes.
17 Okay? Thank you.

18 MS. BROWN: I appreciate it, Your Honor. Thank you.

19 (Recess at 12:42 p.m. until 12:50 p.m.)

20 THE COURT: All right. I don't want to butcher your
21 name. Etminan?

22 THE WITNESS: That's right.

23 THE COURT: Dr. Etminan, would you raise your right
24 hand, please.

25 MAHYAR ETMINAN, PharmD, MSC, PLAINTIFFS' WITNESS,

1 after having affirmed, was examined and testified as follows:

2 THE WITNESS: Yes.

3 THE COURT: State your full name, sir.

4 THE WITNESS: Mahyar Etminan.

5 THE COURT: All right. The lawyers are going to ask
6 you some questions. Let's get started.

7 MS. BROWN: May I proceed, Your Honor?

8 Thank you.

9 DIRECT EXAMINATION

10 BY MS. BROWN:

11 Q. Good afternoon, Dr. Etminan. How are you?

12 A. I'm good. Thank you.

13 Q. My name is Alli Brown, and I have some questions for you
14 on behalf of the folks at ZHP and the other defendants. Okay?

15 A. Okay.

16 Q. All right. And to set the stage, Doctor, I understand
17 that in this case you've written a report, and you are of the
18 opinion that exposure to NDMA and NDEA can cause nine
19 different types of cancers; is that right?

20 A. That's right.

21 Q. Okay. And the methodology, Doctor, that you used to form
22 that opinion, as I understand it, was a systematic search of
23 the scientific literature and a systematic appraisal of the
24 available evidence. Does that sound familiar, sir?

25 A. Yes.

1 Q. Okay. And essentially what you did, Doctor, is you
2 conducted a literature search. Correct?

3 A. That's right.

4 Q. Okay. And then you performed a Bradford Hill analysis on
5 a subset of the literature that you looked at. Is that fair?

6 MR. VAUGHN: Object to the scope, Your Honor.

7 If I may explain myself.

8 THE COURT: Sure.

9 MR. VAUGHN: Dr. Etminan's entire declaration is just
10 him explaining and providing evidence of how the defense took
11 a partial quote from his report out of context. The scope of
12 his cross should be limited as to whether he was taken out of
13 context and if the contents of his declaration are the correct
14 context. Allowing the defense to revisit topics which they
15 have already extensively deposed Dr. Etminan on will only
16 reward and incentivize their tactics.

17 THE COURT: No, I understand. And we're not getting
18 far afield. Don't worry about it. But I think some
19 background information is certainly relevant here as to how he
20 arrived at his opinions, and then we'll move into the
21 declaration.

22 MR. VAUGHN: Thank you, Your Honor.

23 THE COURT: Go ahead.

24 MS. BROWN: Thank you, Your Honor. Appreciate it.

25 BY MS. BROWN:

1 Q. So just to reorient us, Dr. Etminan, after doing the
2 literature search, I understand you did a Bradford Hill on a
3 subset of some of the literature you found. Right?

4 A. I did a Bradford Hill on the studies or the evidence that
5 met my inclusion criteria that are laid out in my report, yes.

6 Q. Understood, sir. And what you mean by that is you
7 determined what studies to include and what studies to exclude
8 in your Bradford Hill. Is that fair?

9 A. That's right.

10 Q. Okay. And to be fair, Doctor, and it's the subject of
11 your declaration that we're getting to right away, you didn't
12 give all of the studies the same amount of weight in your
13 analysis. Is that true?

14 MR. VAUGHN: I'm going to relaunch my objections to
15 scope.

16 THE COURT: Well, I understand that, but I think it's
17 pretty obvious that none of the experts in this case or any
18 case ever gives equal weight to all the studies.

19 MS. BROWN: I understand.

20 THE COURT: I think we can all guess at what the
21 answer is, but go ahead.

22 MS. BROWN: Thank you.

23 THE COURT: Let's move along.

24 BY MS. BROWN:

25 Q. And that's true, right, Doctor, is that you made a

1 determination about what weight to give to what studies.

2 Correct?

3 A. That's right.

4 Q. And that was part of your methodology. Right?

5 A. Correct.

6 Q. Okay. And in your declaration in this case that we're
7 here to talk to you about, you talk about two studies that you
8 gave little weight to. Right?

9 A. That's right.

10 Q. Okay. And what you tell us in your declaration at
11 paragraph 3 is that you gave little weight to studies called
12 Gomm and Pottegard; is that right?

13 A. Correct.

14 Q. Okay. And in terms of all the studies cited in your
15 report, those are the only two studies that evaluated exposure
16 to NDMA and NDEA from valsartan, the medicine. Right?

17 A. That's right.

18 Q. Okay. And the other studies you relied on, sir, were
19 occupational or dietary studies. Is that true?

20 A. True.

21 Q. Okay. And neither of the two studies, Gomm or Pottegard,
22 that you gave little weight to, neither of those two studies
23 found an association between exposure to the medicine
24 valsartan and overall cancer risk. Right?

25 A. Generally speaking, yes, although they did show some

1 increase in risk of some cancers, but globally, even they
2 looked at all cancers. I believe Pottegard showed a very
3 small increase in risk that was not statistically significant,
4 and Gomm I believe showed an increase in risk with liver
5 cancer only.

6 Q. So in terms of the analysis, though, of whether exposure
7 to these compounds from the medicine valsartan increased the
8 overall risk of cancer, both of these studies found no
9 association with the overall risk of cancer.

10 Would you agree with that, sir?

11 A. Again, I'd like to be a bit more specific.

12 With Pottegard, they do report a 9 percent increase in
13 risk that was not significant statistically; nevertheless,
14 they do present a 9 percent increase in risk.

15 Q. And, actually, though, when Pottegard reports that
16 nonstatistical finding, they report it as no association with
17 an overall cancer risk. Right, sir?

18 A. That's what they report.

19 Q. Okay. And when you say in your declaration, that that's
20 the issue of the question in here, sir, you say that you gave
21 these studies little weight, because in your view, these
22 studies were what you call inconclusive. Right?

23 A. I came to the conclusion that they were inconclusive as a
24 result of a number of limitations that I also discuss in
25 detail.

1 Q. Okay. And the word "inconclusive," that's your word.
2 Right? The word "inconclusive," it doesn't appear in either
3 of those articles. Correct?

4 A. That's my word, yes.

5 Q. Okay. And, in fact, Doctor, you wrote a letter to the
6 authors of the Pottegard study about whether or not the study
7 was inconclusive. Do you remember that?

8 MR. VAUGHN: Object to the scope. Your Honor, this
9 is completely outside of what's in his declaration, and it's
10 been taken out of context.

11 MS. BROWN: May I be heard, Judge?

12 THE COURT: Well, I need to know what's in the
13 letter, to be honest with you, to find out whether this is
14 relevant to what's in his declaration. So you can ask him
15 about what he wrote, what was the point, what was the purpose
16 of the letter and all that kind of stuff.

17 MS. BROWN: Thank you, Your Honor.

18 BY MS. BROWN:

19 Q. And so just to set the stage, Doctor, and get us all on
20 the same page, paragraph 3 of your declaration, you tell us
21 that these two studies were inconclusive in your view. Right?

22 A. Yes.

23 Q. And that's why you gave them in your analysis little
24 weight. Correct?

25 A. Yeah.

1 Q. Okay. And the idea of whether or not the Pottegard study
2 was inconclusive or not, as you say in your declaration,
3 that's something that you've actually raised with the author
4 of the Pottegard study. True?

5 A. I remember that I did write a letter. I don't remember
6 the details, but I did read -- write a letter, yes, bringing
7 up some of the points that I also bring up in the report
8 regarding the study.

9 Q. Okay. And what I'd like to do is hope -- we'll see if we
10 can do it, but hope that I can share my screen.

11 We'll mark as Etminan-1 a copy of that letter. And I'm
12 going to see if I can show it to everyone here.

13 Okay. So can everyone see that? Most importantly the
14 Judge and you, Doctor?

15 A. Yes.

16 Q. Okay. Terrific.

17 All right. And so let's just orient ourselves about --
18 this letter is coming from you in September of 2018. Right,
19 sir?

20 A. Yes.

21 Q. Okay. And you're writing this letter to the author of
22 one of the two studies that you determined was inconclusive,
23 and therefore, you gave it little weight. Right?

24 A. That's right.

25 Q. Okay. And the title of your letter to the author

1 actually uses the word "inconclusive." Right, sir?

2 A. Yes.

3 Q. What you title your letter is: Epidemiologic Study of
4 NDMA-Contaminated Valsartan Use and Risk of Cancer, Reassuring
5 or Inconclusive? Right?

6 A. Yes.

7 Q. And you had a series of comments about whether or not the
8 findings were reassuring or inconclusive that you asked the
9 authors about. Right?

10 A. Yes.

11 Q. And there were some other folks who also sent some
12 letters. Right?

13 A. Yes.

14 Q. Okay. And you know that the authors responded to you.
15 Right?

16 A. Yes.

17 Q. Okay. And in the authors' opinion, sir, in answering the
18 question you raised, are the findings reassuring or are they
19 inconclusive, the authors actually told you and others that
20 they were -- the findings were reassuring. Right?

21 Let's take a look at what they said.

22 This is from around the same time, from the Pottegard
23 author responding to your letter and somebody else's letter.
24 And the authors say: While we can't rule out a small increase
25 even several magnitudes larger than the one estimated by the

1 FDA, our estimates do provide some reassurance that no major
2 increase in cancer incidence could be detected.

3 Do you see that?

4 A. Yes. That's their opinion. Yes.

5 Q. So as to the question you raise to the very authors of
6 the study, are they inconclusive or are they reassuring, the
7 authors, the folks who wrote the study, believed the results
8 were reassuring. True?

9 A. That's what they say, yes.

10 Q. Okay. And they also answered directly, sir, some of the
11 issues and critiques that you raise in your declaration.
12 Isn't that right?

13 A. If you could put it back. It's been a while since I saw
14 that letter, so if I could just --

15 Q. Absolutely. Fair enough, sir. Let me help orient us a
16 little bit.

17 I'm going to your declaration here to get us oriented to
18 another critique you tell us in your declaration and a
19 critique that you raise with the authors --

20 A. Sorry, can I see the response from the authors again?
21 That's what I meant.

22 Q. Oh, sure. Absolutely, sir.

23 A. Thank you.

24 Q. I don't know if we can put it in the chat so that --
25 okay.

1 This is what we were looking at, Doctor, the response
2 from the author. Right?

3 A. Okay. So can I just have a few minutes just to read the
4 whole response?

5 Q. Oh, yeah, absolutely. And there's another response I
6 want to show you.

7 This is a response to Dr. Zhou that we were looking at.
8 He's the other author attached here. And then there was a
9 specific response that I wanted to show you, addressed to
10 yourself. Okay?

11 A. Okay. Can I then just -- if you want to ask me about the
12 responses, can I read them all, please, and then --

13 Q. Absolutely. Absolutely. What I want to ask you about is
14 what I have highlighted here, which is a response to you
15 specifically. And I'll just put it up. I don't know if I can
16 zoom it in. If you want a minute, just tell me when you're
17 ready to go to the next page.

18 A. Okay.

19 Can you please flip the page?

20 Q. Sure thing. Absolutely.

21 A. Okay.

22 Q. So one of -- going back to your declaration that's the
23 subject of our questioning here today, in telling the Court in
24 this declaration that you gave limited weight to these studies
25 because you found them to be inconclusive, you listed a number

1 of specific critiques about the study.

2 Are you with me?

3 A. Yes.

4 Q. Okay. And on one of them is that the authors didn't
5 account for the possibility that a patient could be switched
6 from a nonNDMA-containing valsartan to an NDMA-containing
7 valsartan during the follow-up period. Right?

8 A. Yes.

9 Q. Okay. And you also raised along the same lines the issue
10 of misclassification of exposure in paragraph number 1.
11 Right?

12 A. That's right.

13 Q. Okay. And that concept is actually something that you
14 had raised when you wrote to the authors of the Pottegard
15 study. Right?

16 MR. VAUGHN: I want to put an objection on the record
17 really quickly.

18 I don't believe that response that you were showing
19 was in regards to Dr. Etminan's email. And the letters that
20 you are showing are not peer reviewed. And they're not
21 experts in this case.

22 THE COURT: Well, wait a minute. I'm really worried
23 about the first. Say the first objection again.

24 MR. VAUGHN: I don't believe that was a response to
25 Dr. Etminan's email to the study authors that she was going

1 over.

2 THE COURT: Oh. Can we ask the witness if he
3 recognizes that as the response to his letter.

4 MR. VAUGHN: I'm having difficulty following you,
5 Ms. Brown. I'm trying to get the exhibits that you're using,
6 and I'm not seeing the stuff that you're showing him.

7 MS. BROWN: No problem.

8 MR. VAUGHN: Thank you.

9 MS. BROWN: We can separately email it to you.

10 And I'll try to make it clear for the record.

11 BY MS. BROWN:

12 Q. Dr. Etminan, I'm going to direct you to a letter that was
13 sent to you.

14 Dear Dr. Etminan. Do you see that?

15 A. That's right.

16 Q. Okay. And I'm going to talk to you about what the
17 authors said.

18 But before we do that, I want to go back to your letter,
19 okay, and talk about another critique that you raised with the
20 authors themselves. Okay? Are you with me?

21 A. All right. Right.

22 Q. So one of the issues that you raised when you -- in your
23 comment about whether it was reassuring or inconclusive, one
24 of the things you raised is the same thing you raised in your
25 declaration, is that it's possible that patients taking -- I'm

1 sorry, folks.

2 That patients taking NDMA valsartan may switch to other
3 generic formulations during follow-up, increasing the
4 possibility of exposure misclassification.

5 Do you see that as something that you raised with the
6 authors?

7 A. Yes.

8 Q. Okay. And to reorient us, that's something that you
9 raised in your declaration to the Court. Right?

10 A. That's right.

11 Q. Okay. And you raised -- you put that in your declaration
12 to the Court as a reason why the study was inconclusive and
13 the reason that you gave it, to use your words, little weight.
14 Right?

15 A. Yes.

16 Q. Okay. But the authors responded to you on this exact
17 point. Right, Doctor?

18 A. Can you please put back the author's response?

19 Q. Sure.

20 MR. VAUGHN: Doctor, do you have access to this
21 entire document so you can review it in its entirety?

22 Ms. Brown, can you provide a copy of the entire
23 document to Dr. Etminan and myself?

24 MS. BROWN: I'd be absolutely glad to. As I
25 understand it, we're prevented from putting it in the chat.

1 If you want give me an email address, we can send it
2 off right now. I do want to make sure he has the ability to
3 look at it.

4 MR. VAUGHN: Mine is brett@hollislawfirm.com. I can
5 forward it to him if you get it sent to me.

6 MS. BROWN: Perfect. I'm sorry. It's Brett what?

7 MR. VAUGHN: @hollislawfirm, H-O-L-L-I-S,
8 lawfirm.com.

9 MS. BROWN: Terrific. We'll get that right to you
10 right now.

11 MR. VAUGHN: And I want to relaunch the objection
12 that this would not be competent evidence. This was not peer
13 reviewed. These are not experts in this case.

14 THE COURT: They don't have to be peer reviewed or be
15 experts in the case. She's asking whether or not his specific
16 complaint or criticism was responded to by the author.

17 MR. VAUGHN: Thank you.

18 THE COURT: That's all we're trying to find out at
19 this point.

20 MS. BROWN: May I proceed, Judge?

21 THE WITNESS: Well, I think you asked me a question,
22 so can I take a couple of minutes to formulate my response?

23 THE COURT: You can take a couple minutes to look at
24 the letter. You have to wait for the letter.

25 MR. VAUGHN: We're waiting on the letter.

1 MS. BROWN: As I understand it, we've sent it to you,
2 Mr. Vaughn, so hopefully it arrives momentarily.

3 MR. VAUGHN: I'll let you know when I receive it.

4 MS. BROWN: Thank you.

5 MR. VAUGHN: All right. I'm forwarding it to him.

6 MS. BROWN: Thank you very much.

7 MR. VAUGHN: Let me know when you get it,
8 Dr. Etminan. And please take your time to review the whole
9 document.

10 BY MS. BROWN:

11 Q. Doctor, have you received the copy?

12 A. Sorry, how am I receiving the copy?

13 MR. VAUGHN: I just emailed it to you.

14 THE WITNESS: Okay. So if I could respond to your
15 first point on the response of the authors to my criticism or
16 however you like me to go about it.

17 BY MS. BROWN:

18 Q. Thanks, Doctor. I wanted to ask you a question about the
19 critique that you raised to the authors about the potential
20 misclassification that you also raised in your declaration.

21 Do you have that question in mind?

22 A. Yes.

23 Q. And in looking at the response, and now you have a copy,
24 that came to you from the authors themselves, they address
25 that critique. Right, sir?

1 MR. VAUGHN: Counsel, will you put the first page of
2 the document up so we can see who it's actually addressed to?

3 MS. BROWN: Yup. Dear Dr. Etminan.

4 MR. VAUGHN: No, that's not the first page of the
5 document. That's page two of the document. The response that
6 you were going over earlier and you're acting like it was
7 forwarded to the Doctor, is titled to Dr. Zhou. Page 1.

8 MS. BROWN: I don't want there to be any confusion,
9 so I'll just address it for the record.

10 BY MS. BROWN:

11 Q. There are a number of letters, right, that you and others
12 sent. And the letter I want to talk to you about right now is
13 a letter addressed to you on the misclassification critique
14 that you raised.

15 Are you with me on that, Doctor?

16 A. Yes.

17 Q. And it's true that what -- that what the author said was
18 that: The ever use analyses do not introduce exposure
19 misclassification. By definition, a patient is considered an
20 ever user after the first NDMA-contaminated prescription fill,
21 regardless of whether the patient uses non-contaminated
22 valsartan later.

23 That was the author's response to the critique you raised
24 in your letter and in the declaration you did for the Court.
25 Correct?

1 A. That's right.

2 Q. And even though the authors, Doctor, responded to you on
3 that critique, you continued to maintain that critique as a
4 reason that you gave Pottegard little weight in your analysis;
5 is that right?

6 A. That's right. Because they address my critique -- they
7 respond to my critique but they don't really address my
8 critique.

9 Q. In their view, sir, the authors believed that their paper
10 and their research did not introduce exposure
11 misclassification. That's what they told you, right, sir?

12 A. That's what they told me. But the reasoning that follows
13 that statement is not satisfying to me, because they're
14 basically saying, look, with respect to misclassification that
15 you're raising, all we did was we made sure that the first
16 prescription was a prescription that had NDMA-contaminated
17 valsartan.

18 Somebody -- that same subject could have been followed
19 later on and received a prescription with a different dose --
20 a different level of NDMA or no NDMA in valsartan during the
21 follow-up of that patient. We didn't really care about that.
22 All we cared about was that the very first prescription was
23 NDMA contaminated.

24 And, again, that goes to my point that if you follow that
25 patient who may be switching from -- you know, different

1 batches of the same formulation which may have different
2 content of NDMA or different manufacturers of, say, valsartan
3 which also may have different levels of NDMA, there is going
4 to be measurement error in the level of NDMA in that patient's
5 follow-up, which can introduce a bias into this study.

6 So to answer your question, they address my comment, but
7 they don't really answer my comment to my satisfaction.

8 Q. Sir, just to be fair, you raised the issue of exposure
9 misclassification with the authors. Right?

10 A. Yes.

11 Q. Okay. And in their response to you, they told you they
12 didn't believe that was an issue in their study, and you
13 disagree with the authors. Right?

14 A. I -- well, they explain -- they explain why there is --
15 there shouldn't be misclassification, but the scientific
16 reasoning that they provide that you're showing in the letter
17 to me is sort of counterintuitive and is not satisfying
18 scientifically.

19 Q. Okay. So when it comes to the issue of misclassification
20 or potential exposure misclassification, you have a different
21 view of that than the authors of the Pottegard study. Is that
22 fair?

23 A. I don't think we have -- misclassification in
24 epidemiology -- if you open an epidemiology textbook,
25 misclassification is one of the major biases that is very well

1 defined. What I'm saying is that the issue of

2 misclassification that I raised is not really answered or

3 addressed by the response that they provided.

4 Q. Okay. Let's move on, Doctor, and let's talk about the
5 two reasons that you give in your declaration for why you
6 found these studies to be inconclusive and why you give them
7 little weight. Okay?

8 A. Okay.

9 Q. And the two issues that you raise in your declaration
10 are, number one, that there was a short duration of follow-up.
11 Right?

12 A. That's right.

13 Q. And, number two, what you say, most importantly, there
14 was an inability in these studies to precisely quantify the
15 amount of NDMA in the valsartan formulations. Right?

16 A. That's right.

17 Q. Those were your two critiques why you gave these studies
18 less weight than other studies you reviewed. Fair?

19 A. I believe in my report I also discuss, perhaps, competing
20 risk analyses, but in my declaration, yes.

21 Q. Right. And I'm trying to limit my questions, sir, to
22 your declaration, so --

23 A. Okay. I appreciate that.

24 Q. -- in your declaration, you tell us about these two.
25 Right?

1 A. Yes.

2 Q. And so I want to start with the one that you tell us is
3 most important to you, and that has to deal with the
4 quantification of NDMA in valsartan in these studies. Okay?

5 A. Okay.

6 Q. Okay. And the fact is, sir, is that this issue of
7 quantification of valsartan exposure is true in all of the
8 studies that you rely on in your report. Isn't that right?

9 A. The issue of quantification of NDMA, yes.

10 Q. Okay. And, in fact, you told us that -- you know, for
11 example, it's an issue in the study that most of your report
12 is based on the Hidajat -- am I pronouncing that correctly?

13 A. Hidajat, yes.

14 Q. Hidajat.

15 MR. VAUGHN: Object to the scope of the question.
16 Hidajat is not mentioned anywhere in his declaration. This is
17 getting far afield.

18 MS. BROWN: And, Your Honor, what is mentioned, of
19 course, are the two critiques of the studies he gave little
20 weight to. And I'm just exploring how that applies to the
21 studies he did give weight to.

22 THE COURT: I'm not following you at all.

23 How could it possibly apply to the studies he gave
24 weight to?

25 MS. BROWN: Well, Your Honor, the critique that he

1 has of two studies that he did not give weight to, right, is
2 the same critique that applies to the studies he did give
3 weight to, so --

4 THE COURT: Well, what do you mean it's the same
5 critique? That's what I'm not understanding. What do you
6 mean by the same critique?

7 MS. BROWN: Sure, Your Honor. He admitted in his
8 deposition, that, for example, the Hidajat study also had to
9 use estimates of NDMA exposure. And in his words, he said
10 it's pretty much impossible to have a precise quantification,
11 which is, of course, the critique he says in his declaration
12 for why he gave little weight to Gomm and Pottegard.

13 THE COURT: Well, it's one of the reasons he cites.

14 MS. BROWN: Correct.

15 THE COURT: Okay. Well, so you want to ask him why
16 he didn't apply the same standard to Hidajat?

17 MS. BROWN: Sure, Your Honor. Basically, the
18 critique he gives the Court for why he didn't give Gomm and
19 Pottegard the same amount of weight is a critique he admits
20 applies to the study he gave the most weight to.

21 MR. VAUGHN: These are not the same critiques he even
22 gives to Hidajat. They don't even -- they're not even able to
23 quantify it in Pottegard and Gomm. It's a completely
24 different critique.

25 MS. BROWN: I just have two questions on it.

1 THE COURT: Well, the Hidajat study is the subject of
2 deposition questioning, I assume. Right? Yes?

3 MS. BROWN: Yes, Your Honor, it is.

4 THE COURT: Okay. Well, you can ask him whether or
5 not he applied the same critique to the studies he relied on.

6 MS. BROWN: Understood. Thank you, Your Honor.

7 BY MS. BROWN:

8 Q. And so just to wrap this up, then, Doctor, and consistent
9 with the Court's order, you were critical of Gomm and
10 Pottegard for not having precise quantification of the NDMA
11 exposure. Right?

12 A. Yes.

13 Q. Okay. But what you told us in your deposition is that
14 that's also a problem with the study you rely on like Hidajat.
15 Right?

16 A. Yes. And, again, every epidemiological study has
17 limitations, but the Hidajat was an environmental epi study
18 that explained in their methodology how they actually measured
19 NDMA for their analysis. The Pottegard and Gomm studies are
20 the only two studies that actually set out to answer this very
21 specific question: Does NDMA in valsartan increase the risk
22 of cancer?

23 So the amount of NDMA in the different dosages is the
24 underpinning of this -- of the question that they set out to
25 answer. And so I had a much higher expectation for these

1 authors to provide information, at least say they attempted to
2 get the information on the amounts of NDMA in valsartan, which
3 they did not do.

4 Hidajat was a different study with a different scope;
5 nevertheless, they did provide the methodology that they used
6 to measure NDMA.

7 Q. Okay. And that methodology, sir, was to rely on
8 estimates of exposure, right, in the Hidajat study?

9 A. Yes.

10 Q. Okay. And you were not critical of the Hidajat author's
11 decision to rely on those estimates. Correct?

12 A. Again, I did mention the Hidajat limitations. I was more
13 critical on the NDMA amounts and concentrations in the
14 Pottegard and Gomm studies because they -- again, this very
15 important issue of NDMA concentration, they mainly relied on
16 one citation that they report. And they made a -- sort of a
17 bold assumption which we know today after knowing the
18 information about the amount of NDMA in these dosages is not
19 true in that they made the assumption that the higher the
20 doses of valsartan, the higher the NDMA. So, again, I wanted
21 to see more sort of discussion -- attempts to get NDMA-level
22 data on these valsartan dosages, knowing that there's a huge
23 variation between manufacturers and within manufacturers,
24 which was not done.

25 Q. And one of the things both Gomm and Pottegard did to

1 address the issue that you're raising is they conducted
2 sensitivity analyses. Correct?

3 A. Yes.

4 Q. Okay. And in both instances, in both studies, those
5 sensitivity analyses produced comparable results. Correct?

6 A. They did. But, again, the underpinning of that
7 sensitivity analysis was the same flaw that I raised in that
8 they assumed that NDMA concentration goes up with increasing
9 the dosages of valsartan, and we know that's not true. We
10 know that high dosages of a valsartan tablet would have a
11 lower concentration of NDMA than a lower dose valsartan. And
12 so the assumption that they used that I criticized their
13 results for, they used the same assumption for the sensitivity
14 analysis, and, hence, they got similar results.

15 Q. Okay. Another reason, Doctor, you've been critical of
16 Gomm and Pottegard is because you said, and you reference it
17 in your declaration, that NDMA exposure was not specified in
18 the control group. Correct?

19 A. That's right.

20 Q. And you told us that you would have liked to have seen
21 the control group broken down by high exposure, medium
22 exposure, and low exposure. Correct?

23 A. That's right.

24 Q. Okay. And the reason for that, Doctor, is because dose
25 and duration are important to determining carcinogenicity.

1 True?

2 A. Yes.

3 Q. Okay. And when it comes to the compounds that are the
4 subject of your report and your declaration and your
5 testimony, NDMA and NDEA are found everywhere. Right?

6 A. That's right.

7 Q. They're in the air we breathe, the food we eat, everybody
8 is exposed to some amount of these compounds. Correct?

9 A. That's right.

10 Q. And in addition to being exposed through food and water
11 and air, our body also makes these compounds. Right?

12 MR. VAUGHN: Object to the scope of the question.
13 She's getting into endogenous formation of NDMA. That's not
14 mentioned anywhere in his declaration. They took him out of
15 context on one quote in his expert report.

16 THE COURT: Ms. Brown, I'm well aware of endogenous,
17 exogenous. It's all through all the papers. Where are we
18 going with this?

19 MS. BROWN: Absolutely, Your Honor. And I'll just
20 tie it up to the critique he raises in his declaration about
21 the quantification. I'm not looking to replot old ground. I
22 promise.

23 THE COURT: Thank you.

24 MS. BROWN: Okay.

25 BY MS. BROWN:

1 Q. And so, Doctor, we're not going to spend a lot of time on
2 endogenous, but you would agree that in addition to exogenous
3 exposure, our bodies make some amount of endogenous NDMA and
4 NDEA as well. Right?

5 A. Yes.

6 Q. Okay. And you are critical of the two papers in your
7 declaration, Gomm and Pottegard, for not quantifying NDMA
8 exposure.

9 But the fact is, Doctor, you haven't attempted to
10 quantify anybody's baseline exposure to these compounds.
11 Right?

12 MR. VAUGHN: Object to the scope. We're going
13 straight to endogenous formation, which is not mentioned
14 anywhere in his declaration.

15 THE COURT: I'm not sure where this is going,
16 Ms. Brown. Where are we going with this?

17 MS. BROWN: Understood, Judge. If I could just have
18 two questions to tie it to the declaration, I'll move on to my
19 next topic.

20 THE COURT: Okay. Let's go.

21 MS. BROWN: Okay.

22 BY MS. BROWN:

23 Q. And what I mean, Doctor, is even though you gave
24 critiques about quantification in your declaration, your work
25 in this case was not aimed at trying to figure out whether a

1 particular increase in exposure to these compounds increases
2 any individual's risk of cancer. Right?

3 A. Can you repeat that question, please?

4 Q. Sure. The work that you did in this case was not aimed
5 at answering the question about whether or not any particular
6 increase in the NDMA or NDEA exposure that people have on a
7 regular basis is enough to cause cancer. Right? You didn't
8 answer that question?

9 MR. VAUGHN: Object to the scope again. Nowhere in
10 his declaration does he discuss an increased risk; he was
11 simply talking about how he was taken out of context.

12 THE COURT: Ms. Brown, you raised this in your motion
13 about this baseline stuff.

14 MS. BROWN: Understood, Judge, and I really --

15 THE COURT: Do we --

16 MS. BROWN: Sorry, go ahead.

17 THE COURT: Do we have to do it again?

18 MS. BROWN: I just want -- I was hoping to get an
19 answer to one question, Judge, because he raises this
20 quantification issue in his declaration. And I just want to
21 make clear, following up on that, that that's not even a
22 question he looked at here.

23 THE COURT: I'm sorry. I didn't hear the end of
24 that. That's not even what?

25 MS. BROWN: That's not even something he's prepared

1 to give an opinion on, Judge, meaning he didn't try and figure
2 out what everybody's exposed to normally and whether
3 particular increases increase your risk of cancer. His
4 question didn't have anything to do with this -- the
5 individual dose or exposure; he just looked at the question in
6 general. And so the critique that he's raising in his
7 declaration is really not tied to any opinion he even is
8 giving in his --

9 THE COURT: Well, no, he's --

10 (Court reporter clarification.)

11 THE COURT: I'm sorry, Ms. Mitchell.

12 Go ahead. Repeat what you were saying, Ms. Brown.

13 The court reporter didn't get it.

14 MS. BROWN: What I was saying, Judge, is that the
15 critique that he's raising on the quantification of these
16 compounds is not tied to any opinion that he's giving in this
17 case.

18 THE COURT: Well, yeah, but the point of the
19 declaration was to respond to criticisms that you, the
20 defendants, have raised.

21 MS. BROWN: Yes, sir.

22 THE COURT: I don't think he's trying to express any
23 new opinions here.

24 MS. BROWN: I understand, Your Honor.

25 THE COURT: Let's move on, please.

1 BY MS. BROWN:

2 Q. Let's move on, then, Doctor, to the second reason you
3 give in your declaration for giving little weight to these two
4 studies. And that has to do with the amount of follow-up that
5 was covered in the studies. Right?

6 A. That's right.

7 Q. Okay. And in Pottegard, the mean follow-up was about 4.6
8 years. Correct?

9 A. The total follow-up, yes.

10 Q. Okay. And in Gomm it was three years. Is that accurate?

11 A. Yes.

12 Q. And you would agree that three to five years is too short
13 a period of time to determine if NDMA in valsartan can cause
14 cancer. Right?

15 MR. VAUGHN: Object. Object to the scope. He does
16 not give any latency opinions in here. He's simply correcting
17 how he was taken out of context and what the correct context
18 is.

19 MS. BROWN: Your Honor, this is a squarely within his
20 declaration as a reason why he disregarded two studies that
21 show no increased risk of overall cancer with valsartan.

22 MR. VAUGHN: You're trying to get him to give an
23 opinion now on how much latency is needed for individual
24 cancers. That's not addressed anywhere in his declaration.

25 THE COURT: He raises the issue in paragraph 3 about

1 the short duration. I think he can be asked what would be an
2 appropriate duration for a study. But you're right about
3 latency. He's not given any opinions about latency periods
4 for any of these cancers. But he can certainly give an
5 opinion about what an appropriate study -- what time frame an
6 appropriate study would encompass.

7 So go ahead, Doctor.

8 THE WITNESS: Yes. So, I mean, there is really no
9 set sort of fixed number of years that has been agreed on as
10 to the optimal follow-up. Obviously, cancer being a latent
11 condition, the longer the follow-up, the more cancers that
12 will develop. So, you know, methodologically, probably better
13 to have longer follow-up.

14 But as I mention in my report, we do -- we are aware
15 of studies of drugs that have caused cancer within a year,
16 being promoters, cancer promoters, similar to NDMA.

17 So again, there is a range, the longer the better,
18 that it could happen, you know, in a year or so, probably less
19 likely than five years or ten years. But, you know, it is
20 possible for a shorter duration as well.

21 BY MS. BROWN:

22 Q. Well, what you told us, sir, before, Doctor, is that
23 three to five years is too short a period of time for cancer
24 to develop from valsartan medicines. Right?

25 MR. VAUGHN: Object. Object to the scope, and you're

1 misstating his prior testimony.

2 MS. BROWN: Well, we can take a look at it. Why
3 don't we take a look at it, Doctor.

4 THE COURT: Well, the Doctor can certainly tell us
5 whether that's his opinion in his prior testimony, but I'm not
6 sure what this has got to do with his declaration. He doesn't
7 opine on latency periods. He just says that these studies
8 weren't following up long enough. And you just asked him,
9 well, how long is long enough, and you got the answer you got.

10 MS. BROWN: I understand, Judge. I'm just looking to
11 test that answer against what his prior testimony was on the
12 years, because he raised it in his declaration.

13 THE COURT: You can ask him what he said at his
14 deposition or whatever about the number of years that would be
15 ideal for a follow-up on the study of NDMA.

16 MS. BROWN: Thank you, Your Honor.

17 BY MS. BROWN:

18 Q. And so Dr. Etminan, you raised the objection to these
19 studies being too short. And you told us in your deposition
20 that three to five years is just not long enough to study --

21 MR. VAUGHN: Objection. You're misstating his
22 testimony. If you're going to quote him, please put it up so
23 we can review it.

24 MS. BROWN: Your Honor, could I get the question out
25 first?

1 THE COURT: Are you asking him whether or not he
2 recalls stating in his deposition that three to five years was
3 not sufficient?

4 MS. BROWN: I am, Judge.

5 THE COURT: Doctor, do you remember saying that at
6 your deposition?

7 THE WITNESS: Honestly, it was a ten-hour deposition,
8 so no.

9 THE COURT: So perhaps counsel can find us a page and
10 line number.

11 MS. BROWN: Sure. Sure, I can.

12 BY MS. BROWN:

13 Q. And Doctor, I'll put it up on the screen.

14 A. I appreciate it.

15 Q. If you have your transcript from 8/25, it looks like it
16 is at page 52. And let me try to get it for you so I can help
17 you.

18 I'll put it up to make it easier.

19 Okay. So we are at page 52 of your deposition, Doctor.

20 And we're looking at line 5. And you were asked this
21 question: I wasn't asking about whether there's a particular
22 individual that might have a shorter latency period than
23 another. I was asking about study design.

24 And what you told us yesterday was that a study period of
25 four or five years, which I believe is the time frame in the

1 Pottegard and Gomm studies, is just too short, and it's too
2 early to tell whether or not nitrosamines in
3 valsartan-containing medications can cause an increased risk
4 of cancer. You need a longer period of time to study that.

5 And your answer on that day, sir, under oath, was yes.
6 Correct?

7 A. Yes. I mean, that is what I say. But again, going back
8 to what I also said, the four to five years being too short,
9 again, the sort of -- there may be some lack of context here.
10 But too short doesn't mean that there won't be any cancers
11 whatsoever. Too short means that optimally we like to see
12 longer follow-ups.

13 And again, back to my declaration, the reasons I gave low
14 weight to these two studies wasn't just because of the short
15 follow-up. I list in detail a number of other limitations,
16 the -- collectively, you know, which collectively led me to
17 giving them a lower rate in terms of their validity.

18 Q. Yes, sir. And in terms of how long you would need a
19 study to figure out whether these compounds in valsartan can
20 increase the risk of cancer, you told us that most cancers
21 take at least ten years to develop. Right, sir?

22 MR. VAUGHN: Objection. That misstates his
23 testimony. Again, we're getting outside of his declaration.
24 We're getting back again to cancer latency in general.

25 THE COURT: Well, no.

1 Doctor, do you remember saying that, about the ten
2 years for most cancers to develop?

3 THE WITNESS: I don't. I don't remember saying that.
4 Again, if you want to -- I could have said it. It's not
5 something that I wouldn't have said it. But specifically in,
6 you know, the context and when I said it or where I said it, I
7 don't remember.

8 THE COURT: Okay. Well, do you agree that that's
9 accurate?

10 THE WITNESS: I would -- again, optimally, the longer
11 follow-ups, like ten years, yes, most cancers would be able to
12 develop that -- as you know, we work with an L-shaped curve in
13 pretty much everything, including cancer, so it doesn't mean
14 that cancers wouldn't develop in shorter periods.

15 And in my report, I do talk about examples of
16 prescription drugs that have been shown to cause cancer within
17 a year. So, you know, it is a wide range.

18 MS. BROWN: And may I just show that testimony, Your
19 Honor?

20 THE COURT: Sure.

21 I don't think he denies giving that testimony, but if
22 you want to show it, that's fine.

23 BY MS. BROWN:

24 Q. So Doctor, we're going to page 50 of that same
25 transcript.

1 And you were asked, do you know the average latency --
2 I'm sorry.

3 Do you know the latency period -- I'm sorry.

4 Do you know the average latency period for colorectal
5 cancer?

6 And your answer was: The latency period for cancer in
7 general is usually around, give or take, ten years.

8 That was your testimony under oath in August of this
9 year. Right, sir?

10 A. Yes. I mean, general that I stand by that.

11 Q. Right. And in terms of this issue that you raise in your
12 declaration about the short duration of follow-up, you were of
13 the view that the Gomm and Pottegard studies shouldn't have
14 even been conducted until more time passed. Right?

15 A. Well, I mean, if you look at Gomm, if you count for
16 latency, meaning that let's say the cancers that happen in the
17 first year after follow-up, there are probably cancers that
18 have started way before the use of the drug.

19 So if you exclude those, they only have maybe about a
20 year of -- or two years of follow-up. That is inadequate.
21 Pottegard had, you know, a bit longer of a follow-up, but Gomm
22 had much less.

23 Q. Right. And what you told us is you should wait until you
24 have adequate follow-up. And these studies that had three,
25 four, four-and-a-half years, shouldn't have even been done

1 until you had adequate follow-up time. Right?

2 A. Well, I mean, optimally that's what you want. Whether
3 you should have waited and not have done this study, again, my
4 concern -- my other limitations that I brought up and you also
5 alluded to by pointing to my letter is the misclassification
6 and the measurement error and other limitations, all of which
7 collectively led me to giving them a lower weight. It wasn't
8 just the follow-up issue.

9 Q. Under -- sorry, sir.

10 A. Yeah, that's it.

11 Q. Okay. But on this issue, when we asked you about this
12 issue, this follow-up issue --

13 A. Uh-huh.

14 Q. -- you said these studies shouldn't have been done
15 because there just simply isn't enough data. Right?

16 A. Is this -- are you going back to my deposition again,
17 or --

18 Q. Yes. Do you want me to show it to you?

19 A. Please.

20 MR. VAUGHN: Doctor, I think you might have a
21 transcript as well, so when she shows it to you, if you need
22 to review other pages for the full context, please feel free
23 to take your time.

24 BY MS. BROWN:

25 Q. We're going to go to the first day, Doctor, to page 172.

1 And we're going to go to line 3.

2 All right. And you were asked this question: And with
3 respect to just discussing the limitation you have identified
4 of time to follow-up, you understand these products were on
5 the market only relatively recently, so approximately 2014 and
6 2018. There's not at the moment an opportunity for any longer
7 follow-up?

8 There was an objection, and your answer was: Yes. I
9 mean, that's the problem. But that doesn't take away from the
10 fact -- I mean, if you can't do this study, you shouldn't do
11 it. You should wait until you have adequate follow-up. You
12 cannot do sort of a -- you cannot disregard an important part
13 of this study design, which is adequate follow-up, because
14 there just simply isn't enough data. I mean, they could have
15 waited until more data is accumulated before they actually did
16 this study.

17 That was your testimony in August of this year. Right,
18 sir?

19 A. Yes. Can you please go maybe a bit higher up right
20 before this?

21 Q. Yeah, absolutely.

22 This Q and A is sort of going to an issue that we talked
23 about earlier, right, sir, the control group?

24 A. Uh-huh.

25 Okay. So can you rephrase your question again, please?

1 Q. Sure. I just want to confirm that the testimony we
2 looked at about whether or not there was enough data available
3 today for the Gomm and Pottegard study design, if this
4 testimony I read to you was accurate?

5 A. Yes. I'm basically saying the longer or the more time
6 you have, the better. And perhaps if the follow-up time that
7 you have is really short, like Gomm, perhaps it's better to
8 wait until more data is accrued and collected to do this
9 study.

10 Q. Doctor, the final area of inquiry for you today has to do
11 with the methodology that's at issue in your declaration.

12 This is not the first time that you have served as an
13 expert witness for plaintiffs' lawyers in litigation. Right?

14 MR. VAUGHN: There's no methodology in his
15 declaration. He's correcting how he was taken out of context,
16 and I don't understand how him being a plaintiffs' expert
17 previously has to do with his declaration.

18 MS. BROWN: May I be heard, Judge?

19 THE COURT: Yeah. What is the methodology that's
20 contained in the declaration?

21 MS. BROWN: Yes, sir. The methodology I think is
22 critical, Judge, because what the declaration deals with is
23 how based on the doctor's methodology, he has decided to give
24 two studies less weight than others in his Bradford Hill
25 analysis. And the fact is, Your Honor, is that he's done this

1 before and his opinion has been excluded because that
2 methodology is unreliable. And that's what I want to ask him
3 about.

4 THE COURT: He's done --

5 MR. VAUGHN: His declar- --

6 THE COURT: Excuse me. He's done what before?

7 MS. BROWN: He's performed a Bradford Hill analysis
8 by disregarding certain information, and that has been found
9 unreliable, and his general causation opinion has been
10 excluded on that basis, Your Honor.

11 THE COURT: And when and where was that?

12 MS. BROWN: That was in the Fosamax case, Your Honor,
13 in the Southern District of New York. And the opinion that
14 excluded his methodology on general causation is from July 27,
15 2009.

16 THE COURT: Do you cite that in your brief?

17 MS. BROWN: Your Honor, I am very new here, and I do
18 not believe so, which is why I was going to ask the doctor
19 about it.

20 THE COURT: So you've never raised this before?

21 MS. BROWN: I'm hoping somebody on the line might be
22 able to step in and help me on this. I apologize, Your Honor,
23 I've only been involved in the case for a few days, but I do
24 not believe this has --

25 MR. VAUGHN: I'm unaware of it being raised.

1 MS. BROWN: -- been part of the briefing.

2 THE COURT: It's not part of the briefing that I can
3 recall or I can find at the moment.

4 The whole purpose of this was really not to get into
5 new issues.

6 MS. BROWN: I --

7 THE COURT: I went to some great extent on Monday --

8 MS. BROWN: I know, Judge.

9 THE COURT: -- with defense counsel about their
10 opportunity to present everything they wanted to present, but
11 I didn't hear a word from you or Mr. Trischler that -- about
12 any of this.

13 MS. BROWN: Yeah. And I apologize. I'm brand new
14 here. As you know, I just entered my appearance. And in
15 looking at the supplemental declaration and understanding
16 completely that we are to tailor our questioning specifically
17 to that declaration, I couldn't help but see that the very
18 same methodology led to this exclusion, and I think it's
19 exactly on point.

20 I mean, there are two reasons he was excluded there:
21 One was disregarding certain information that, you know, went
22 the other way, as we would argue these two studies do; and two
23 is even doing a Bradford Hill analysis in the face of not
24 having an association between the drug and the injury, which
25 we would argue is the same here. So the exclusions seem sort

1 of directly on point here, Your Honor, and --

2 THE COURT: Wait a minute.

3 You're suggesting there's no evidence of an
4 association between NDMA and cancer?

5 MS. BROWN: No, Your Honor. It's between the
6 medicine.

7 So I think what this Court was holding is that you
8 would have to have established causation between the drug --
9 before you even do the Bradford Hill. Right? The Court in
10 two parts -- one, the Court questioned what happened here,
11 right, which is where you sort of give little weight to
12 certain studies and exclude it on that basis. But, two, the
13 Court also said, Your Honor, look, we're questioning whether a
14 Bradford Hill under these circumstances is even appropriate
15 where it hasn't been conclusively established that there's an
16 association between the medicine. Right? Not the compound,
17 not the, you know, contaminant, but the medicine and the
18 injury.

19 And so on those two points, Judge, it seems, you
20 know, kind of on the four corners here of what's happened in
21 this case.

22 MR. VAUGHN: Your Honor --

23 THE COURT: Wait a minute, wait a minute, wait a
24 minute, Mr. --

25 MR. VAUGHN: Sorry.

1 THE COURT: Wait a minute, wait a minute.

2 Yeah, I think you're correct. The Third Circuit, in
3 order to get to causation, you have to establish association,
4 and then you apply either the Bradford Hill principles or the
5 weight of the evidence principles to that to give your
6 causation opinion. Okay?

7 And I don't know what happened in Zolof with this
8 witness. I don't really care.

9 But are you suggesting that the plaintiffs in this
10 case have not established the association element of that
11 requirement?

12 MS. BROWN: Yes, Your Honor. In terms of the
13 medicine, I am. So I understand they're relying on sort of
14 general studies, food studies, occupational studies, about the
15 compound itself. But I would suggest, Your Honor, because
16 dose is so important, Your Honor, that they would -- before
17 they even get to a Bradford Hill, they would have to establish
18 that at this dose, these trace levels are generally capable of
19 causing the nine cancers.

20 THE COURT: Ms. Brown, that's very clever, but
21 perhaps you can explain to me why there was the recall by all
22 these government agencies if there's no association.

23 MS. BROWN: I understand, Your Honor, completely.
24 And I would suggest, though, that regulatory decisions like
25 that are often not in complete concert with the law on

1 causation and particularly the law on Daubert, Your Honor.

2 And I understand out of an abundance of caution,
3 there were actions taken by the FDA. I understand that
4 completely. But I would suggest, Your Honor, just on the
5 methodology, that this Fosamax opinion is enormously
6 instructive and I think raises real questions about the
7 analysis that this doctor did.

8 THE COURT: We'll set aside all the government
9 agencies around the world who decided there's an association,
10 therefore, we have to order a recall.

11 What about the statements made by the officers,
12 employees of the defendants, the vice presidents and officers
13 who clearly state that this stuff is a human carcinogen?
14 That's not an association? Your clients think it is. Why is
15 more even required?

16 MS. BROWN: I understand that completely, Judge. And
17 I guess I would just say this. Like I would use, Your Honor,
18 asbestos as an example, let's just say. Right? I mean, we
19 would all agree asbestos is a carcinogen. Everybody agrees
20 asbestos causes cancer. But at the same time, the EPA allows
21 a certain amount of asbestos in our drinking water. Right?
22 We know that everybody's exposed to asbestos. We all have
23 asbestos in our lungs. And we know that the FDA has recalled
24 products because of a concern about potential asbestos
25 contamination; but we know upon further investigation, those

1 products don't have enough asbestos in them to cause cancer.

2 So I would just suggest to the Court, I completely
3 understand, you know, the concept that this is, you know, a
4 substance that in certain circumstances may be able to cause
5 cancer, but I think the inquiry has to be here for this Court
6 in this circumstance, in this medicine, could it do it? And I
7 would suggest to Your Honor that these experts just on their
8 own admissions haven't done that.

9 THE COURT: There is no answer to the question yet in
10 science. You have two sides to this question. You have two
11 groups of experts totally opposed to each other in this case
12 as to what the science says, which is not really unusual, I
13 think you'll admit, because you've been involved in a lot of
14 cases. Right?

15 MS. BROWN: Yeah, Judge, a lot of cases like this
16 with trace contamination where you've got to figure out how
17 much, you know? I mean --

18 THE COURT: No, I get it. But that's the fun of
19 being a lawyer, because who knows. I mean, you take it to a
20 jury, and the jury says, well, I know --

21 MS. BROWN: I know.

22 THE COURT: I think that what you're trying to --

23 MS. BROWN: Yeah. There is like an initial -- you
24 know, we got to obviously get past -- they have to get past
25 you, Judge, as the gatekeeper. Right? And I would just

1 suggest to the Court that means they have to be able to show
2 in the way that these plaintiffs were exposed, can it
3 generally cause cancer? And that requires an analysis that I
4 would submit hasn't been done here, and that, you know, the
5 Fosamax court excluded on those very grounds.

6 THE COURT: Well, I don't see any parallel between
7 this and the Fosamax case, because I think -- I really do
8 believe that the association element has been clearly
9 demonstrated, both through all the action by the government
10 agencies and through the words of the defendants themselves.

11 So now we're at weight of the evidence, and now we're
12 its -- where it gets tricky, Bradford Hill. And the jury's
13 going to have to hear all this argument, and, you know, you're
14 going to -- defense is going to cross-examine vigorously the
15 plaintiffs' experts. And they're doing a great job so far of
16 doing it, and the jury's going to have to determine.

17 But I don't see any basis that this Fosamax case
18 should at all influence what I think of the declaration of
19 this witness. So let's move on, please.

20 MS. BROWN: Okay. Understood, Your Honor.

21 I think with that, Your Honor, I can conclude.

22 Could I submit the opinion to the Court, though, for
23 consideration, the Fosamax --

24 THE COURT: Just give me the citation. I'll look at
25 it, then, you know --

1 MS. BROWN: Okay. Terrific.

2 Your Honor, it's In re: Fosamax Products Liability
3 Litigation, 645 F. Supp. 2d 164 (2009). And I would direct
4 the Court to -- at 187 is where the discussion of Dr. Etminan
5 begins.

6 THE COURT: Okay.

7 MS. BROWN: I appreciate it, Judge. Thank you.

8 And thank you, Doctor, for your time. I don't have
9 any more questions.

10 THE WITNESS: Thank you.

11 THE COURT: Mr. Vaughn, did you want to ask any
12 questions?

13 MR. VAUGHN: Yes, if that's okay.

14 THE COURT: Sure.

15 MR. VAUGHN: Are we good to start now?

16 THE WITNESS: Sure.

17 MR. VAUGHN: You're on mute, Judge, Your Honor.

18 THE COURT: Ms. Brown, when do you have to leave?

19 It's almost 2:00.

20 MS. BROWN: I just had my paralegal say -- tell me
21 when the judge gets on. So I think I'm okay for right now.
22 We have --

23 THE COURT: If you're going to start at 2:00, then
24 let's not, you know, interrupt in the middle of a question.

25 How long are you going to be on with this other

1 judge?

2 MS. BROWN: I just am going to be on, Judge, for 30
3 minutes or less, if I can, and if that would be okay, with
4 your indulgence.

5 THE COURT: That's fine.

6 Who is this judge?

7 MS. BROWN: It's Judge Licht in Rhode Island, Your
8 Honor. I have a case set for trial up there in the spring.

9 THE COURT: Okay. All right. Well, then why don't
10 we break till 2:30.

11 MS. BROWN: I appreciate it, Your Honor.

12 THE COURT: And we'll come back on at 2:30, and we'll
13 go from there. Okay? Thank you.

14 MS. BROWN: Thank you very much, Judge.

15 Thanks, everyone.

16 (Recess at 1:56 p.m. until 2:32 p.m.)

17 THE COURT: Go ahead. Let's get started.

18 CROSS-EXAMINATION

19 BY MR. VAUGHN:

20 Q. Dr. Etminan, what was the purpose of your declaration?

21 A. The defendants had brought up a few issues regarding my
22 report, so that's what I tried to clarify, some of those
23 issues in my declaration.

24 Q. And what were you trying to clarify exactly?

25 A. That I had disregarded the valsartan-specific studies,

1 mainly the studies from Gomm and Pottegard.

2 Q. And did you disregard the studies, Pottegard and Gomm?

3 A. I did not. I allocate two pages of my report to each
4 study. I summarized the study design and the study findings
5 and then provided line-by-line detailed discussion of the
6 methodology and its limitations.

7 MR. VAUGHN: Thank you, Dr. Etminan. I have no
8 further questions.

9 THE COURT: Ms. Brown, do you have any questions on
10 that?

11 MS. BROWN: I do not. Thank you, Your Honor.

12 THE COURT: All right. Well, look.

13 I did look at the Fosamax case. First off, the
14 ground wasn't raised in the motion to exclude the doctor's
15 opinion. But having looked at the Fosamax case, I'm not
16 impressed.

17 He was permitted to testify on the limitation of
18 certain clinical trials. But the problem there in that case
19 for this witness was, as the court noted, there really wasn't
20 any associational evidence and there was no methodological
21 reason for him to have gotten to Bradford Hill without first
22 the association of evidence.

23 Here that's completely different. As I've said --
24 and I understand Ms. Brown's point that there is no strong --
25 there is no association evidence as to the particular

1 prescribed medicine that was contaminated and the ultimate
2 tumors that are formed. In fact, the two studies which we've
3 spent a lot of time talking about seem to indicate that
4 there's not a lot of strong associational evidence, although
5 they do indicate an increased risk of certain cancers.

6 Anyway, I've already decided that there is strong
7 associational evidence, so there was no reason why Dr. Etminan
8 could not get to the Bradford Hill factors in this case. So I
9 don't think the Fosamax case is terribly helpful.

10 All right. This is what I want to do, folks. I want
11 to take just a couple more minutes, give me about ten more
12 minutes. And then I want to come back on the record and talk
13 about some things. Okay? So give me ten minutes. Thank you.

14 MS. BROWN: Thank you, Your Honor.

15 THE WITNESS: Can I be dismissed or --

16 THE COURT: Yes, Doctor. We're done. Thank you.

17 THE WITNESS: Thank you. Thanks, everyone.

18 (Recess at 2:36 p.m. until 2:48 p.m.)

19 THE COURT: Okay. Anybody wants to join back in and
20 listen, I want to go back through some things with you at this
21 point.

22 Ms. Mitchell, are you ready?

23 All right. I want to go through some of these
24 witnesses, these experts, and tell you my decision on your
25 motions.

1 Let me first thank you for the extraordinary work you
2 did on these motions. I mean, you put in a heck of a lot of
3 time and effort. A heck of a lot of thought went into these
4 things. It was very illuminating in many instances.

5 I follow up what I said on Monday, that I think some
6 of you may have misunderstood my role in all this, but we'll
7 get into all that.

8 The declarations I think were helpful but not
9 dispositive.

10 Let's start with Dr. Lagana, who, by the way, said
11 something very interesting during his testimony today, which
12 may be obvious, but it needed to be said. And that when these
13 experts are determining which studies they want to rely on and
14 which studies they don't want to rely on, there is an element
15 of human judgment involved in this.

16 And I think that's true of every expert on both sides
17 of this case. I don't think that's objectionable at all.

18 But anyway, the first issue that we dealt with and
19 you dealt with in your motions to bar his testimony about this
20 null hypothesis, he explained in his certification,
21 particularly starting at paragraph 3, that he starts with
22 certain assumptions when he's doing a differential diagnosis
23 of a patient, and indeed, that is good medical practice. And
24 he talked about it.

25 And I think we all know that if a doctor prescribes a

1 medication to someone and they come back to the doctor
2 complaining of certain side effects and the doctor knows that
3 that medicine has those known side effects, there is no reason
4 why she should have to start with a null hypothesis. And I
5 think it's pretty clear that what he was talking about applied
6 only to the clinical practice of medicine.

7 Now, defendants also complained that he uses
8 different methodology than he does in his job as a
9 pathologist, and they point to the Benicar case and the use of
10 slides. But he explained all that. And I think that Benicar
11 really is not a good comparison. And Benicar slides had to be
12 examined in order to diagnose the specific injury that was
13 involved, because if you didn't have a specific injury, you
14 couldn't file suit in that case.

15 Furthermore, examination of the slides in the Benicar
16 case yielded no information whatsoever on the cause of those
17 diseases. Just as would be here, I don't see how in a general
18 causation opinion examination of any slides of these tumors is
19 going to tell you how they were caused.

20 Defendants also raised the issue of, again, which
21 studies he relied on, which studies he didn't rely on, why
22 didn't he give certain weight to some studies, why did he give
23 so much weight to other studies. And this is a complaint that
24 both sides have as to every single expert in this case. And
25 this is about the cherry-picking of the data. But really

1 that's what experts do. They look at the data, they decide
2 and they express their reasons why some data is more important
3 at arriving at their opinions than others.

4 So long as they explain how they come to their
5 opinions, and so long as they attempt to explain why they
6 didn't think contrary data is not relevant to their opinion,
7 then that's not objectionable.

8 His opinion about increased risk is not
9 controversial. It's not an ipse dixit assertion that he
10 makes. I think you also need to look at the whole picture.
11 Like I said, like the Third Circuit has said, we're not
12 looking for better experts and better opinions, we're just
13 looking at what's there and whether or not methodology was
14 followed.

15 And what he did in this is he employed the usual
16 research in finding and discussing relevant animal studies,
17 observational studies and other data. He does discuss the
18 contrary data. Noting the associational evidence, he moves on
19 to the Bradford Hill Principles to render his conclusion of
20 general causation. He has an opinion as to how these
21 chemicals can cause cancer. The alkylating agent or the
22 activation, as he explains, of oncogenes. Accordingly, I find
23 no problems with his methodology, and the motion to bar his
24 testimony is denied.

25 Dr. Panigrahy, I think there was a misunderstanding

1 by defense counsel here as to what he was talking about in his
2 certification, and that's the concept of bioavailability.
3 According to him, bioavailability is not dependent whatsoever
4 on saturation. They're really not related, except if you
5 reach a total saturation point, then the bioavailability
6 increases to 100 percent. But he's very clear that there is
7 NDMA that escapes through the liver into the bloodstream, and
8 he relies on animal studies to do that.

9 Now, I've talked about animal studies. We all are
10 aware that there are certain shortcomings of animal studies.
11 But folks, that's what researchers use, particularly where you
12 can't do human studies, as you can't do here.

13 And I think it's important that we remember, and I
14 referred to this earlier about the words of some of the
15 defendants and some other scientists about how this substance,
16 it can be dangerous, how the substance can lead to cancer. I
17 think the associational evidence is certainly sufficient to
18 get this to the jury.

19 Dr. -- Mylan's senior director Lance Molnar testified
20 about the categorization of nitrosamines by the regulatory
21 bodies as -- he talked about non-threshold or not subject to
22 the presumed acceptable thresholds set forth in applicable
23 guidelines and set forth in EMA, et cetera. And that means a
24 single molecule could be detrimental. And that's from his
25 deposition.

1 Here as to Panigrahy, the defendants complain about
2 the heavy reliance on Hidajat. Of course there are
3 limitations. I've talked about that already.

4 But this is a jury question. The jury is going to
5 have to determine which of these studies they think are
6 important and which are not for the reasons that you're going
7 to illustrate to them.

8 Defendants complain that the daily accepted intake
9 level is an improper proxy for general causation. The problem
10 is, once again, that the various government agencies have
11 determined that NDMA is a probable carcinogen. These public
12 health guidelines alone of course cannot establish general
13 causation, but he never claims that they do.

14 He has an opinion about the development of cancer in
15 downstream organs, how much NDMA survives the liver. And
16 again, it's based on animal studies and based on these studies
17 that show, for whatever reason, the larger the animal species,
18 the greater the amount that escapes through the liver.

19 There's nothing new about extrapolating from animal
20 studies, particularly here where apparently every species of
21 animal seems to have been studied and seems to have developed
22 cancer.

23 He uses the same methodology he would in his own
24 research, and of course the jury doesn't have to believe
25 anything he says, but that's up to them. So the motion is

1 denied.

2 Etminan, the most recent witness, defendants complain
3 that he does not calculate or consider baseline NDMA or NDEA
4 exposure. And that, frankly, is a weakness in all the reports
5 that I've seen. Based on the exposure apparently meaning that
6 you have to measure what people eat, what they drink, where
7 they live, what they breathe; all contributing to baseline
8 exposure. That's not fatal, because again, the methodology
9 Dr. Etminan uses is sound.

10 And again, the defendants raise the issue of, you
11 know, he raised -- he relies on some studies and not others.
12 And in his declaration and in his testimony today, we spent a
13 lot of time talking about why the Gomm and the Pottegard
14 studies weren't terribly helpful in arriving at his opinions.

15 The jury may reject that. They're free to reject
16 that, and you're free to argue to the jury that they have to
17 reject that.

18 Defendants complain of his reliance on Hidayat. And
19 they say, well, you know, he didn't apply the same standards.
20 Well, he did, as far as I could tell, apply the same standards
21 as to why he accepted some and not others. I'm not going to
22 be the one to determine whether these are good studies or bad
23 studies.

24 The defendants raised the issue that he misapplies
25 his own criteria, things of that nature. He did examine a

1 significant number of studies. Again, he provides an
2 explanation as to why some are noteworthy and some aren't.
3 Again, this is a jury question.

4 Defendants complain he misapplies Bradford Hill.
5 This again is a disagreement as to what studies are
6 significant and what aren't, particularly the Hidajat study.

7 Again, you need to focus on the big picture,
8 the whole picture, what has he done in this and what has he
9 not done. We're not trying to find a better expert report,
10 we're just trying to find out if he follows accepted
11 methodology, which I find that he has.

12 Defendants are correct, though, about the NDEA.
13 There's very little on that. And there's -- he can express an
14 opinion as to the association between NDEA and pancreatic
15 cancer because that's the only data apparently that's
16 available, but he cannot express an opinion as to NDEA
17 exposure in esophageal, stomach, colorectal, liver, lung,
18 bladder or prostate cancer. So the motion is denied except as
19 to those cancers.

20 I'm going to go through some of the ones who have not
21 testified because there's no point in waiting on that, because
22 that's not going to change.

23 Hecht, Stephen Hecht, H-E-C-H-T.

24 This is again another complaint about failure to
25 consider dose threshold for his conclusion that NDMA and NDEA

1 cause cancer at the levels present in this
2 valsartan-containing drug. But the FDA and other regulatory
3 agencies have already done threshold level calculations. And
4 he's entitled to rely on those. Again, the jury doesn't have
5 to agree, but he's entitled to rely on those.

6 There's the issue of extrapolation from animal
7 studies. I've spoken about this. There's no reason to
8 continue that discussion.

9 I understand that the point being made by defense
10 counsel about the high doses of these substances that are
11 force-fed to these animals, but I think the experts will tell
12 you and have told us that's just the way they do the test,
13 primarily because of the relatively short lifespan for these
14 animals. And the FDA and the EMA and all the regulatory
15 agencies rely on these animal studies.

16 Defendants complain that Hecht didn't do any
17 independent testing. Well, nor did most other people in this
18 case. They complain there's no definitive study that shows
19 that these drugs, these contaminants cause -- any of these
20 drugs cause cancer. Well, that's true. But again, it's a
21 difficult proposition, because you cannot do any human
22 clinical studies because of the danger of this drug.

23 And remember Daubert. The opinion expressed does not
24 have to be generally accepted in the scientific community.
25 What has to be accepted is the way you go about doing your

1 research.

2 The methodology he uses is the same as everyone else.
3 He examines all the studies that are available, he explains
4 why he thought some were not terribly helpful or relevant and
5 why some were. The jury will have to straighten this out.

6 And there's an issue about background exposure. He
7 acknowledged that. Others did also, did not take into account
8 background exposure. But again, you need to focus on the
9 whole picture, what was done and what wasn't done. These
10 weaknesses in all these experts are certainly going to be
11 fertile ground for counsel in examining and cross-examining
12 these experts.

13 What he does do is refer to the various government
14 agencies and their findings. He analyzes the studies. He
15 discusses the defendants' own statements and explains why he
16 believes the contrary studies, Pottegard, Yoon, everyone else,
17 are not terribly helpful. Accordingly, the motion is denied.

18 David Madigan. Defendants complain he does not give
19 an opinion on general causation, and indeed he does not. He's
20 only going to be offering opinions on the strength of
21 association evidence, which as we know is the beginning of the
22 road that may lead to causation by applying Bradford Hill or
23 weight of the evidence.

24 Defendants, interestingly enough, cite cases in which
25 Madigan's been barred from testifying as to certain opinions.

1 And one of them is the incretin, I-N-C-R-E-T-I-N, case, which
2 interestingly is going to be argued Monday in the Ninth
3 Circuit. I'm not sure whether the Madigan issue has been
4 raised in that because I didn't read the briefs in that case.
5 But that might be interesting to tune in.

6 But the incretin case really doesn't apply, because
7 in that case the court noted that there were absolutely no
8 studies or animal experiments or clinical trials or
9 observational studies or any analysis that a single researcher
10 or organization had up to that point concluded that incretin
11 caused pancreatic cancer. And indeed, the FDA had spent a
12 decade studying it and had consistently said that there was no
13 causal association even between incretin and pancreatic
14 cancer.

15 This is entirely different from our case here. We
16 have numerous studies that make the argument and numerous
17 government agencies who found that these substances are
18 probably carcinogenic.

19 In incretin, Madigan also had an updated history for
20 it, and he had changed his methodology and the opinion he was
21 going to offer. Actually, probably I would have barred anyway
22 but not on Daubert grounds because I didn't think it was very
23 relevant anyhow.

24 But anyway, in Vioxx he was permitted to express his
25 opinion on the statistics.

1 And the other cases they rely on I don't think are
2 controlling this question.

3 The defendants claim that it's really an
4 epidemiological opinion and of course he's not an
5 epidemiologist. He's a statistician. But all epidemiological
6 conclusions are based on statistics. Of course metaanalyses
7 are only as good as the underlying data. Distortions do
8 exist. But that doesn't mean they aren't recognized in the
9 scientific community. Many disciplines, sociology, you name
10 it, use metaanalysis. They are recognized in scientific
11 circles as having some value.

12 Defendants claim he only reviewed studies that were
13 hand-picked for him. But he uses studies cited by Etminan,
14 who did a thorough review, which Fryzek, the defense expert,
15 comments favorably on.

16 The defendants' claim about his conclusions from
17 Hidajat, I don't need to further comment on that.

18 There's the issue of dose, timing, duration of
19 individual exposure, and the defendants rely on the Hoffeditz,
20 H-O-F-F-E-D-I-T-Z, case from the District of New Jersey about
21 the single exposure, single molecule theory. And indeed, that
22 case did condemn that.

23 But it was applying Pennsylvania asbestosis law in
24 that case. And under Pennsylvania law, you had to prove that
25 the exposure was frequent, regular and proximate. And the

1 testimony that each and every exposure of asbestos is
2 causative of mesothelioma, it was not permitted. But that was
3 Pennsylvania law about asbestos. That's not really the law
4 here. And incidentally, the expert was permitted to testify,
5 because the amount of exposure was significant.

6 Defendants further complain he makes an impermissible
7 inferential leap from dietary and NDMA occupational exposure
8 to pharmaceutical exposure. Again, how and why experts rely
9 on certain studies and not on other studies is a jury
10 question.

11 We raise the issue again about NDEA because you only
12 have the Zheng, Z-H-E-N-G study. Madigan does say that NDEA
13 and NDMA are similar, however, he provides no explanation as
14 to how that is so, and he provides no analysis of bladder,
15 breast, kidney, pharyngeal, or uterine cancers. Consequently,
16 he will not be permitted to testify about NDEA. Otherwise,
17 that motion is denied.

18 Turning to some of the defense experts who are not
19 going to be giving testimony, John Flack, F-L-A-C-K,
20 plaintiffs point out that he has no experience with NDMA or
21 NDEA, has no background in toxicology or oncology or cancer
22 research and doesn't consider a lot of the relevant
23 literature. He acknowledged in his deposition that his
24 opinion would be quote, blasted, B-L-A-S-T-E-D, in the
25 academic world.

1 I find he does not consistently apply any recognized
2 methodology to his opinions, but he does have experience in
3 treating hypertension. And therefore, he is competent and
4 capable of testifying that hypertensives have a higher
5 incidence of cancer, and obese hypertensives, an even higher
6 risk of cancer because of these underlying conditions.
7 Otherwise, the motion is granted and he'll be barred from
8 testifying about anything other than these two.

9 Janice Britt, B-R-I-T-T, this one is simple.
10 Although Daubert and other cases hold that the conclusions
11 don't necessarily have to be supported by general acceptance
12 in the relevant scientific community, the methodology must be
13 acceptable.

14 The problem for Britt is that the methodology she
15 uses, EBT, is not recognized in the scientific community as a
16 standard used by toxicologists to weigh dangers caused by any
17 substance. She didn't even use the EBT methodology that she
18 describes. So that one's easy, and that motion to strike her
19 opinion is granted.

20 John Fryzek, F-R-Y-Z-E-K. I have to comment
21 that there are all kinds of interesting cross-examination
22 materials here: The employment discrepancies, the resume
23 discrepancies, the alleged professorships at Vanderbilt and
24 elsewhere that apparently weren't so, the absolutely baffling
25 billing discrepancies in this case and in the Welding Rod MDL.

1 But this is all ammunition that you can use for
2 cross-examination, and we'll see what the jury says about it.
3 It has nothing to do with the issues that I need to decide.

4 His methodology is he says that he did a systematic
5 literature review based on certain standard techniques. He
6 looked for studies that described the risk of cancer with
7 exposure to valsartan-containing drugs, and he looked for
8 studies that described the risks of cancer with dietary
9 exposure to NDMA and NDEA. By definition and by his search
10 terms, he probably missed some.

11 But his methodology in and of itself is not
12 objectionable. He says that his search yielded 1,884 results
13 on these studies. He reduces that to 109 articles using, he
14 says, his criteria. He added 8 by a process I don't really
15 understand. But that leaves 117 which he examined in full.
16 He eliminated 92 for various and sundry and good reasons, so
17 he ends up with, you know, a couple dozen. And of course,
18 like all defense experts, relies heavily on Pomm, P-O-M-M,
19 Pottegard, P-O-T-T-E-G-A-R-D, Al-Kindi, A-L-K-I-N-D-I, and
20 Yoon, Y-O-O-N.

21 He reviews the same studies as plaintiffs' experts
22 which plaintiffs show -- claim show a connection between NDMA
23 and various cancers, but he disagrees with those conclusions.
24 He criticizes the plaintiffs' experts in much detail and the
25 studies they rely on in an attempt to distinguish them. For

1 having used the basic methodology, that motion to bar his
2 testimony is denied.

3 Lee-Jei Wei, it's L-E-E dash J-E-I, last name W-E-I.
4 I'm sure I'm not pronouncing that correctly. I assume that
5 the sole purpose of his testimony is to refute Madigan's
6 findings and the data that Madigan relied on.

7 The plaintiffs raise some interesting points, which
8 probably deserve some comment. The witness seems to have used
9 a template from other cases he had written reports on. He
10 spends pages discussing human clinical trials which have
11 absolutely no relevance to this case.

12 And as to his methodology, his criticism of
13 metaanalysis, again, a technique used in all scientific
14 disciplines, results in no metaanalysis passing his test. He
15 states no recognized methodology that can lead one to this
16 result, thus, he will not be permitted to testify about
17 metaanalysis.

18 There's no basis for any opinion he has on lifetime
19 cumulative exposure, LCE. He's never done any calculation,
20 can't even approximate the amount of NDMA in these medicines
21 and doesn't have any idea how Madigan calculated it. Thus,
22 the basis for his criticism of Madigan's calculation is
23 unknown, and he won't be permitted to testify about that.

24 He also -- it's hard to tell -- it's hard to tell
25 about a lot of what he says. He's hard to follow in his

1 deposition. And I'm sure plaintiffs are going to have fun
2 cross-examining him on some of the things he said about, you
3 know, society being better off, et cetera, et cetera. But to
4 the extent he's trying to express opinions that exposure to
5 NDMA does not cause cancer, that will be prohibited, because
6 as best as I can determine, the only basis for that opinion
7 is, well, Madigan makes the connection and Madigan is wrong,
8 so therefore the opposite must be true.

9 So he's not going to be permitted to offer any
10 opinion that exposure to NDMA will not result or increase the
11 risk of any cancers. Other than that, he has methodology, he
12 cites to certain techniques he says Madigan should have used
13 and should have followed, and he's permitted to testify about
14 those things.

15 All right. The only two we have left. And plaintiff
16 apparently wishes to question or -- Bottoroff and Johnson if
17 they want.

18 Have we made arrangements for a time to start on the
19 15th? Or are you still working on that, guys? What's going
20 on?

21 MS. LOCKARD: Your Honor, we can have our witnesses
22 here, you know, if you want to start around the same time,
23 9:30. We are -- we have worked it out so that we can have
24 Dr. Johnson and Dr. Bottoroff both on the 15th, if that still
25 works. So we'll plan to proceed at this point. I don't know

1 exactly who will be first, but I can let Your Honor know when
2 we know that.

3 THE COURT: That's fine. That's great.

4 I think the plaintiffs need to decide whether they're
5 going to go through with the exercise first. But anyway, if
6 they do, I'll be here.

7 All right. I think that concludes what we're doing
8 today. Thank you, everybody. Have a great evening, and we'll
9 see you in a couple of weeks.

10 RESPONSE: Thank you, Your Honor.

11 (Proceedings concluded at 3:18 p.m.)

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15 I certify that the foregoing is a correct transcript
16 from the record of proceedings in the above-entitled matter.

17

18 /S/ Ann Marie Mitchell, CCR, CRR, RDR, RMR
19 Court Reporter/Transcriber

20

21 4th day of March, 2022
22 Date

23

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